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(54) **Title:** EPITHELIAL DELAMINATING DEVICE (V) AND BLADES USEFUL IN THAT DEVICE

(57) **Abstract:** The described device is useful in the field of ophthalmology. The blades, devices, and methods for using them involve separating or lifting corneal epithelium from the eye in a substantially continuous layer to form an epithelial tissue member typically still attached to the cornea. The epithelial tissue member often is in the form of a flap or pocket. In particular, the devices utilize a non-cornea-cutting, oscillating blade that operates as a separator or dissector that is configured for example, by structure and lubricity, to separate the epithelium at naturally occurring cleavage surfaces in the eye, particularly between the epithelium and the corneal stroma (Bowman's membrane), specifically separating in the region of the lamina hicida. The blade may be blunt and have an open region away from the dissector edge for providing lower frictional forces against the separated epithelium. The blade may have a blunt dissecting edge possibly made by first forming an edge sufficiently sharp cut epithelium and then electropolishing that edge to a substantially blunt edge appropriate for separating the epithelium from the cornea without cutting the cornea. The blade may be at least partially coated with one or more lubricious materials, preferably on the surfaces adjacent the epithelium during use. The separated epithelium may be lifted or peeled from the surface of the eye to form an epithelial flap or pocket. The epithelium may then be replaced on the cornea after a refractive procedure or replaced onto an ocular lens after placement of that ocular lens on the eye.

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EPITHELIAL DELAMINATING DEVICE (V) AND BLADES USEFUL IN THAT DEVICE

FIELD

[0001] The described device is useful in the field of ophthalmology. The blades, devices, and methods for using them involve separating or lifting corneal epithelium from the eye in a substantially continuous layer to form an epithelial tissue member typically still attached to the cornea. The epithelial tissue member often is in the form of a flap or pocket. In particular, the devices utilize a non-cornea-cutting, oscillating blade that operates as a separator or dissector that is configured for example, by structure and lubricity, to separate the epithelium at naturally occurring cleavage surfaces in the eye, particularly between the epithelium and the corneal stroma (Bowman's membrane), specifically separating in the region of the *lamina lucida.* The blade may be blunt and have an open region away from the dissector edge for providing lower frictional forces against the separated epithelium. The blade may have a blunt dissecting edge possibly made by first forming an edge sufficiently sharp cut epithelium and then electropolishing that edge to a substantially blunt edge appropriate for separating the epithelium from the cornea without cutting the cornea. The blade may be at least partially coated with one or more lubricious materials, preferably on the surfaces adjacent the epithelium during use. The separated epithelium may be lifted or peeled from the surface of the eye to form an epithelial flap or pocket. The epithelium may then be replaced on the cornea after a refractive procedure or replaced onto an ocular lens after placement of that ocular lens on the eye.

BACKGROUND

[0002] Refractive surgery refers to a set of surgical procedures that change the native optical or focusing power of the eye. These changes alleviate the need for glasses or contact lenses that an individual might otherwise be dependent on for clear sight. The majority of the focusing power in the human eye is dictated by the curvature of the air-liquid interface, where there is the greatest change in the index of refraction. This curved interface is the outer surface of the cornea. The refractive power of this interface accounts for approximately 70% of the total magnification of the eye. Light

rays that make up the images we see pass through the cornea, the anterior chamber, the crystalline lens, and the vitreous humor before they are focused on the retina to form an image. It is the magnifying power of this curved, air-corneal interface that provided the field of refractive surgery with the opportunity to surgically correct visual deficiencies.

[0003] Initial refractive surgical procedures corrected nearsightedness by flattening of the curvature of the cornea. The first largely successful procedure was called radial keratotomy (RK). RK was widely used during the 1970's and early 1980's where radially oriented incisions were made in the periphery of the cornea. These incisions allowed the peripheral cornea to bow outwards, consequently flattening the central optical zone of the cornea. This was fairly easy and thus, popular, but it rarely did more than lessen one's dependency on glasses or contract lenses.

[0004] A largely flawed and failed procedure called epikeratophakia was developed in the era of RK. It is now essentially an academic anomaly. Epikeratophakia provided a new curvature to the outer curvature of the cornea by grafting onto the cornea a thin layer of preserved corneal tissue. Lyophilization is the preservation method used in epikeratophakia where the cornea is freeze-dried. The tissue is not acellularized but is rendered non-living. During the process of freeze drying, the cornea is also ground to a specific curvature.

[0005] The epikeratophakia lens was placed into the eye surgically. An annular 360° incision was placed into the cornea after completely removing the epithelium from where the epikeratophakic lens would sit. The perimeter of this lens would be inserted into the annular incision and held in place by a running suture. There were several problems with epikeratophakia: 1) the lenses remained cloudy until host stromal fibroblasts colonized the lens, which colonization possibly could take several months; 2) until migrating epithelium could grow over the incision site onto the surface of the lens, the interrupted epithelium was a nidus for infection; and 3) epithelium healing onto the surgical site sometimes moved into the space between the lens and the host cornea. Currently, epikeratophakia is limited in its use. It is now used in pediatric aphakic patients who are unable to tolerate very steep contact lenses.

[0006] Major industrial research efforts tried to produce a synthetic version of the epikeratophakic graft called the synthetic onlay in a synthetic epilens. Different synthetic polymers were used (hydroxyethylmethacrylate, polyethylene oxide, lidofilcon, polyvinyl alcohol). Hydrogels of these materials normally did not have a

surface that was readily conducive to epithelial cells growing and adhering onto these synthetic surfaces. This was one of the major setbacks of synthetic onlays. Epithelial cells could not adequately heal onto these lenses.

[0007] Another problem with these synthetic lenses is that they did not adhere well to the surface of the eye. Conventional suturing was difficult and the use of biological glues was also flawed. Glues were not ideally biocompatible in the cornea.

[0008] Lastly, the permeability of these hydrogels was significantly limiting. Living epithelial cells on the surface had difficulty achieving adequate nutrition. Corneal epithelial nutritional flow is from the aqueous humor through the cornea out to the epithelial cells. In the end, industrial efforts failed to develop an adequate synthetic epikeratophakic lens.

[0009] Around the mid 1990's procedures that sculpt the cornea with lasers were sufficiently successful that they began to replace radial keratotomy. The first generation of laser ablation of the cornea was called photorefractive keratectomy (PRK). In PRK, an ablative laser (e.g., an excimer laser) is focused on the cornea to sculpt a new curvature into the surface. In PRK, the epithelium is destroyed when achieving a new outer surface curve. Over the ensuing post-operative days, the epithelium has to grow or heal back into place. This epithelial healing phase was problematic for most patients since the epithelially denuded and ablated cornea was painful. It is also initially difficult to see, and this "recuperative time" can last from days to a week or more.

[0010] A subsequent variation of PRK corneal laser ablation, LASIK, has become very popular. The LASIK procedure, also known as laser in situ keratomileusis, is synonymous in the public mind with laser vision correction. In LASIK, an outer portion (or chord-like lens-shaped portion) of the cornea (80 to 150 microns thick) is surgically cut from the corneal surface. This is performed by a device called a microkeratome. The microkeratome is a device which cuts a circular flap from the surface of the cornea which remains hinged at one edge. This flap is reflected back and an ablative (excimer) laser is used to remove or to reform a portion of the exposed surgical bed. The flap is laid back into place. When this flap is laid back into place, the cornea achieves a new curvature because the flap conforms to the laser-modified surface. In this procedure, epithelial cells are not removed or harmed. The epithelial cells have simply been incised at the edge of this flap. When the flap is placed back onto the corneal bed, the epithelium heals back at the incision site. There is essentially no recuperative time and

the results are almost immediate. Because there is very little surgical time (15 minutes for each eye) and because there are lasting and very accurate results, LASIK is currently considered the premier manner of performing refractive surgery.

[0011] The newest technique being evaluated in high volume refractive surgical practices and in some academic centers is a procedure called **L**aser **A**ssisted Subepithelial **K**eratomileusis (**LASEK**). In LASEK, a "flap" is made of only epithelium. This layer of epithelium is lifted off the cornea in a manner similar to LASIK. The ablative laser is focused just on the surface of the denuded cornea (in the same manner as was done with PRK). However, this epithelial flap is left intact, i.e., epithelium is not destroyed. It is simply rolled back into place after formation of the re-curved anterior portion of the cornea, resulting in much less recuperative time than with PRK. Current methods of LASEK are not as good as LASIK but the results are better than with PRK.

[0012] The corneal epithelium is a multilayered epithelial structure typically about 50 μm in thickness. It is non-cornified. The outer cells are living, although they are squamous in nature. The basal epithelial cells are cuboidal and sit on the stromal surface on a structure known as Bowman's membrane. The basal cell layers are typically about 1 mil thick (0.001"). The basal cells produce the same keratins that are produced in the integument, i.e., skin. The basal epithelial cells express keratins 5 and 14 and have the potential to differentiate into the squamous epithelial cells of the corneal epithelium that produce keratins 6 and 9. The corneal epithelium has a number of important properties: 1) it is clear; 2) it is impermeable; 3) it is a barrier to external agents; and 4) it is a highly innervated organ. Nerves from the cornea directly feed into the epithelium, and thus, defects of this organ produce pain.

[0013] Epithelial cells are attached side-to-side by transmembrane molecules called desmosomes. Another transmembrane protein, the hemidesmosome, connects to collagen type 7 and is present on the basolateral surface of basal epithelial cells. Hemidesmosomes anchor epithelium to the underlying collagenous portion of the stroma. The junction between the epithelium and corneal stroma is referred to as basement membrane zone (BMZ).

[0014] When LASEK is performed, a physical well is placed or formed on the epithelium and filled with a selection of 20 percent ethanol and balanced salt solution. Contact with the solution causes the epithelial cells to lose their adherence at the BMZ,

most likely by destroying a portion of that cell population. The epithelium is then raised by pushing the epithelium, e.g., with a Weck sponge, in a manner similar to striping a wall of paint. The exposed collagenous portion of the corneal stroma is then ablated to reshape its surface. A weakened epithelium is then rolled back into place to serve as a bandage. However, this "bandage" fails to restore the epithelium to its original state, i.e., it does not preserve the integrity of the epithelium, thereby reducing its clarity, impermeability to water, and barrier function. Furthermore, the ability of the epithelium to adhere to the corneal stromal surface is impaired.

[0015] U.S. Patent Nos. 6,099,541 and 6,030,398 to Klopotek describe a microkeratome apparatus and method for cutting a layer of corneal epithelium to prepare the eye for LASIK or other reshaping procedures. The epithelium, if replaced, is attached using surgical techniques.

[0016] None of the cited references shows or suggests my invention as described herein.

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SUMMARY

[0024] The description includes blades, separators, or dissectors that are sufficiently blunt that they do not cut the cornea stroma (e.g., Bowman's Layer) but will pass through the epithelium and along the sub-epithelial corneal surface without cutting the cornea. The non-cutting blades form an epithelial tissue member in the form of a generally continuous layer of epithelium separated or lifted from its supporting underlying structure perhaps as a flap or a pocket, generally connected at least one edge to the cornea. The formed epithelial tissue member may be used in conjunction with a refractive surgical procedure or with placement of refractive lens.

[0025] The blade may have an opening in the blade body that lowers friction between the blade body and the epithelium or cornea as it forms the epithelial tissue member or is retracted after forming the member. Additionally, or in the alternative, the blade may have an edge formed by electropolishing a previously sharper edge.

[0026] The epithelial delaminator may comprise one or more lubricious materials on at least the surfaces of the delaminator that contact the epithelium during the delamination and withdrawal steps.

[0027] The delaminator blades may comprise a combination blade also configured to carry an optical device, e.g., a lens, for implantation during the procedure.

[0028] The epithelial delaminator devices including these blades are mechanical separators in nature. They are mechanical delaminators that typically vibrate or oscillate the blade and may provide for translational movement of the blade during formation of the epithelial tissue member.

[0029] Furthermore, the method of this invention may be used variously to de-epithelialize the cornea in preparation for a reshaping procedure such as LASEK or to form a pocket for inclusion of a contact lens.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] FIG. 1 is a perspective view of a posterior or bottom surface of a corneal blade and implant applicator.

[0031] FIG. 2 is a perspective view similar to FIG. 1 in which the corneal blade includes a cover on the posterior surface.

[0032] FIG. 3 is a perspective view of an anterior or top surface of the corneal blade of FIG. 1 with a corneal implant located on that surface.

[0033] FIG. 4A is a magnified side view of the distal end of the FIG. 3 blade.

[0034] FIG. 4B shows a magnified cutaway side view of the distal end of the FIG. 4A blade.

[0035] FIG. 5A is a top view of another version of an ocular device applicator useful in separating the corneal epithelium and inserting an ocular device between the cornea and the corneal epithelium.

[0036] FIG. 5B is a side view of the FIG. 5A ocular device applicator.

[0037] FIG. 5C is a bottom view of the FIG. 5A ocular device applicator.

[0038] FIG. 6A is a top view of another variation of an ocular device applicator having a central opening and an implant beneath the applicator in that opening.

[0039] FIG. 6B is a bottom view of the FIG. 6A ocular device applicator.

[0040] FIG. 6C is a side view of the FIG. 6A applicator also showing an implant lens to be placed.

[0041] FIG. 7A is bottom view of another ocular device applicator.

[0042] FIG. 7B is a perspective section view through line L-L' of FIG. 7A.

[0043] FIG. 8A shows a perspective view of the top of an applicator similar to the applicator of FIG. 7A.

[0044] FIG. 8B shows a perspective view of the bottom of the applicator of FIG. 8A.

[0045] FIG. 8C shows a perspective view of the bottom of the applicator of FIG. 8A with a cover plate installed.

[0046] FIG. 9A is a top view of a variation of a blunt blade useful in separating the corneal epithelium.

[0047] FIGS. 9B1 and 9B2 are side (or axial) cross-sectional views of the FIG. 9A device.

[0048] FIG. 9C is an end, cross-sectional view of the FIG. 9A device.

[0049] FIG. 10A is a top view of a second variation of a blunt blade epithelial separator.

[0050] FIG. 10B is a side or axial, cross-sectional view of the FIG. 10A device.

[0051] FIG. 10C is an end, cross-sectional view of the FIG. 10A device.

[0052] FIG. 10D is a close-up, side, sectional view of a portion of the FIG. 10A device.

[0053] FIGS. 11A, 11B, 11C, and 11D show, respectively, a top view, a cross-sectional side view, a partial close-up side view, and a partial close-up side view of a variation of a variation of the delaminator blade having physical friction-lowering features.

[0054] FIGS. 12A and 12B show, in schematic fashion, the production of a blunt edge of a cutting blade using electropolishing, the resulting blade being suitable for delaminating the epithelium without entering the corneal stroma.

[0055] FIGS. 13A and 13B provide schematic top and sectional front views of one variation of a cutting blade having passageways for introduction of fluids during use.

[0056] FIGS. 14A and 14B provide schematic bottom and sectional front views of another variation of a cutting blade having passageways for introduction of fluids during use.

[0057] FIGS. 15A – 15D show sections of various blade leading edge profiles.

[0058] FIGS. 16A – 16C show top views of various leading edge subsection angles.

[0059] FIGS. 17A-17G show a variation of the delaminator cutting blade and its component parts and lens, as shown in FIGS. 1-4B, respectively, in side section view of the blade, in top view of the blade, in top view of the implant onlay, in bottom view of the sealing/fluid routing plate, in bottom view of the blade without the cover plate in place, in top view of the sealing/fluid routing plate, and in end view of the sealing/fluid routing plate.

[0060] FIGS. 18A-18E show a variation of the delaminator cutting blade and its component parts and lens, in which the lens is bottom-mounted during placement. The figures show, respectively, a side section view of the blade and lens, a bottom view of the blade, a top view of the implant onlay, a top view of the blade and a magnified side section view of the blade and lens.

[0061] FIGS. 19A-19E show, respectively, the top view, a cutaway side-view, a cutaway end view, a partial cutaway side-view showing a single lubricious surface, and a partial side-view cutaway showing more than one lubricious surface, all of a spatula shaped epithelial delaminating member.

[0062] FIG. 20A shows a top view of a circular epithelial delaminator.

[0063] FIG. 20B shows a cross-section side-view.

[0064] FIG. 20C shows an end view cross-section.

[0065] FIGS. 20D and 20E show partial side-view cutaways depicting single and multiple lubricious surfaces to the FIG. 20A delaminating element.

[0066] FIG. 21A shows a top view of another variation of a block-like epithelial delaminator.

[0067] FIG. 21B shows a side-view of that delaminating member.

[0068] FIGS. 21C and 21D show partial cross-sectional side-views of the delaminator with lubricious coverings, respectively, on the epithelial contact regions, and on the whole delaminator.

[0069] FIG. 22A shows a top view of a corneal epithelial delaminator having a dome shaped area and a recess opposite the dome area.

[0070] FIG. 22B shows a cross-section end view.

[0071] FIG. 22C shows a side-view of the FIG. 22A delaminating member.

[0072] FIG. 22D shows a side-view cross-section of the FIG. 22A delaminating member.

[0073] FIGS. 22E and 22F, show, respectively, the FIG. 22A delaminator with a single lubricious surface and multiple lubricious surfaces.

[0074] FIG. 23A shows a top view of a wire whip epithelial delaminating member.

[0075] FIG. 23B shows a free movement of the whip of the delaminating member.

[0076] FIG. 23C shows constrained movement of the whip delaminating member of FIG. 23A and the shape of one lifted epithelial region created using moving constraint point.

[0077] FIG. 23D shows the wire delaminating member having lubricious material adjacent the epithelium.

[0078] FIG. 23E shows the wire delaminator member with lubricious coating over its surface.

[0079] FIG. 23F shows a cross section if the wire delaminator member with a partial lubricious covering over its surface.

[0080] FIG. 24A shows a small oval delaminating member.

[0081] FIGS. 24B, 24C, 24D, and 24E show various movements suitable for use with the FIG. 24A delaminating member and certain lifted epithelial regions made using the combined motions.

[0082] FIGS. 24F and 24G show, respectively, cross-sections of the delaminating member of FIG. 24A having the epithelial surfaces coated with lubricous material and all the surfaces coated with lubricious material.

[0083] FIGS. 25A and 25B show, respectively, a vibrator or dissector assembly having the blunt blade in a generally non-extended position and in an extended position.

[0084] FIGS. 26A, 26B, 26C, and 26D generically show steps for utilizing the blunt blade and dissector assembly described herein.

DETAILED DESCRIPTION

[0085] FIG. 1 shows a version of a corneal epithelium inserter/delaminator blade 8. The blade 10 comprises a body 12. As shown in FIG. 1, the body 12 has a first surface 14, a first end 16, and a second end 18. Once again, to clarify: when used in reference to cutting devices used to place an implant or lens on the surface of a de-epithelialized cornea (an "onlay") rather than below the surface of the surface of the cornea, the functional "cutting" ability of the blade 10 or body 12 may be expressed as being able to penetrate the epithelium and to separate the epithelium from the Bowman's membrane and to form a pocket opening. Typically, the leading edge profile or shape, bluntness of or the "lack of sharpness" of the body determines that functional parameter, although it need not be the exclusive determinant of that ability. For instance, a motion applied to the body 10 may be so chosen to enhance or to diminish the scope of the "cutting" functionality of the device as it relates to various components of the eye. Should this device be used to penetrate the Bowman's Layer for eventual placement of an inlay-type implant, the functional "cutting" ability of the device would be quite enhanced.

[0086] In reference to the Figures, and in reference to uses only when the cutting system is used to penetrate the epithelium and to separate it from the cornea, the first surface 14 may be understood to be a posterior or bottom or rear surface of the body 12. This first or rear surface 14 faces the patient or cornea during use. In addition, the first or distal end 16 may be understood to be a distal end of the body 12, and the second end 18 may be understood to be a proximal end of the body 12. The distal end 16 initially contacts a surface of the eye during a surgical procedure.

[0087] The blade 10 may include a plurality of openings 20 located at a distal end region 22 of the body 12. As described in detail herein, the openings 20 may also be

understood to be ports, such as vacuum and/or fluid delivery ports. The openings 20 may extend through the body 12 from the first surface 14 to an opposing second surface 30 (as shown in FIG. 3). The openings 20 are illustrated as being arranged in two concentric circles; however, other cutting devices may have more or fewer openings arranged in other configurations.

[0088] As depicted, channel 24 extends through the extension of body 12 to provide a fluid delivery path to the openings 20. As shown in FIG. 1, channel 24 extends from the distal end region 22 to the proximal end 18 where the channel 24 terminates at a port 26. The port 26 may be understood to be a vacuum or ejection fluid port or cooling fluid port. Clearly, one or more channels such as channel 24 may be used.

[0089] FIG. 2 shows the same view of the blade 10 as does FIG. 1, but with a cover 28 situated over the channel 24 (now hidden) and, in this variation, covering the various openings 20 as seen in FIG. 1. The cover 28 is placed over the channel 24 to effectively seal channel 24 so that a vacuum can be created near the openings 20 as seen on the opposite surface (30 in FIG. 3). For example, a vacuum device or a source of suction may be connected to the port 26 to create a vacuum in the channel 24 and the at the distal end region 22. Although the cover 28 is illustrated as a separate element attached to the body, such channel or channels may be integrated or formed within such an extension 13 during production of the blade 10, e.g., by drilling or extrusion or the like. In such variations, a cover would not be required since the channel could be a bore or lumen extending through the body extension 13.

[0090] FIG. 3 shows the top or second surface 30 with a corneal onlay 32 ready for implantation beneath the epithelium. In the variation shown, a vacuum, a negative pressure or reduced pressure relative to atmospheric pressure, is provided to retain a corneal onlay 32 on the blade 12 during its passage to the placement site, penetrating the corneal epithelium and separating it from the Bowman's layer. As shown in FIG. 3, the body 12 has a second surface 30 that can be understood to be a top surface, an anterior surface, or a front surface of the blade 12. The corneal onlay 32 is illustrated as being retained on the second surface 30.

[0091] In other variations shown herein, the corneal onlay 32 is retained on the first or bottom surface 14, i.e., the surface adjacent the cornea during the delamination step.

[0092] The corneal onlay 32 is shown as being located at the distal end region 22 of the blade 12. In this illustrated variation, the distal end region 22 has a maximum

diameter that is slightly greater than the maximum diameter of the corneal onlay. For example, the maximum diameter of the distal end region 22 may be about 1% to about 30% larger than the maximum diameter of the corneal onlay 32. In this variation, the maximum diameter or width of the distal end region 22 is substantially similar to the maximum diameter of the corneal onlay so that the maximum diameter or width of the pocket opening to substantially match the maximum diameter of the corneal onlay. This sizing results in reduced movement or decentration of the onlay in the pocket.

[0093] FIG. 4A shows a side view of the distal end region 22 of the body 12. The distal end region 22 includes a sloped edge 34 extending around the perimeter of the onlay supporting portion 35. For example, the distal end region includes a chamfered edge surface 34 extending around the sides and distal end 18 of the distal end region 22, and a sloped edge surface 36 extending around a proximal portion of the onlay 32. In the variation shown in FIG. 4A, the chamfered edge surface 34 terminates at a measurable distance from the first surface 14. This distance between the outermost edge of the chamfered surface 34 to the first surface 14 is reflected by surface 38. The sloped edge surface 36 retains the corneal onlay in position at the distal end region 22 of the blade 10 during an implant procedure. The sloped edge 36 also serves to reduce movement of the corneal onlay 32 if the vacuum pressure is interrupted or otherwise insufficient to retain the onlay.

[0094] FIG. 4B shows a cross-section side-view of the distal end section 22 shown in FIG. 4A. The positioning of the onlay 32 upon the onlay supporting region 35 is clearly shown. The vacuum/fluid release fluid/cooling fluid access holes 20 and their relationship to the onlay 32 are also apparent from the drawing. The position of the sealing plate 28 is also shown. Optional chamfer 29 is shown to be supporting the sealing plate 28. As will be discussed in more detail below, a lubricious layer 31 is also shown.

[0095] Other designs for the blade 10 are described below. In the variations that comprise dual functions of corneal epithelial delaminators and ocular device inserters, we may also interchangeably call such components "cutting device," "delaminator," "applicator," or "ocular device applicator."

[0096] As discussed elsewhere herein, a continuous layer of corneal epithelium may be separated from or lifted from the anterior surface of the eye by applying various mechanical forces to this anterior surface, or to the basal cell layer, or to the junction

between the basal cell layer and the Bowman membrane (the "lamina lucida"). The term "continuous" as used herein means "uninterrupted". More or less epithelium may be separated from the cornea. Although the various devices and methods disclosed herein may be used to create a loose flap of corneal epithelium, e.g., less than 50% (often between about 10% and about 50%) of the edge of the delaminated epithelium remains attached to the cornea, our devices are preferably used to provide a pocket of corneal epithelium, generally leaving between 50% and 75 % of the edge of the delaminated epithelium attached to the cornea. A half flap, or tight pocket, of delaminated corneal epithelium may also be formed by leaving between 50% and 95% of the edge of the delaminated epithelium attached to the cornea.

[0097] In particular, the applicators described herein allow an ocular device to be inserted onto the delaminated cornea, beneath the epithelium that was separated from the cornea. The separated epithelium can then be allowed to return to atop the inserted ocular device.

[0098] Another variation of an applicator, the combined delaminator/inserter comprises a blunt tool 40 as is seen in FIG. 5A. In general, these applicators have an elongated shape terminating in an edge region 42. Overall, this version of the applicator may be substantially flat, as shown in the profile of the applicator in FIG. 5B. This applicator includes a top 54, or upper, surface and a lower, or bottom, surface 56. The bottom surface 56 is shown in FIG. 5C. The region of the applicator facing the delaminated corneal surface is the bottom 56 surface of the applicator 40 and the region of the applicator facing the delaminated corneal epithelium (or adjacent to the underside of the epithelium during the insertion step) is the top 44 surface. The applicator is shown as substantially flat, and having a uniform thickness 50 across its length, although other shapes (e.g. non-uniform thicknesses, "wedge" shapes, etc) are also intended to be encompassed by this description. FIG. 5C also illustrates an ocular device holder (or holding region), shown as a cavity 60 in the bottom surface into which at least a portion of an ocular device fits.

[0099] In operation, the applicator 40 may be attached to an applicator mount or a handle, so that it may be controlled by a user. As will be discussed below, such an applicator mount may include or be connected to a driver motor in such a way that the edge or blunt tip region 42 moves in a repetitive, oscillatory motion that separates corneal epithelium from its underlying tissue without cutting that stromal tissue. The

edge 42 may be configured to move in at least one of a side-to-side motion and an up-and-down motion. The edge may also be moved in a circular or semi-circular motion, for example, following a radius smaller than the diameter of the tip region.

[00100] The edge 42 of the applicator 40 is the region which mechanically interacts with the cornea to delaminate the epithelial region from the surface of the cornea. The edge region may therefore have any shape which facilitates this interaction. In cross-sectional profile, the edge region is shown as a wedge-shaped angle in FIG. 5B, but the edge 42 may be of other profiles, e.g., pointed, flattened or curved. The cross-sectional profile of the edge may be of any degree of bluntness, from the very blunt to very sharp (approaching a knife edge). The cross-sectional profile of the edge may also vary over the length of the edge. Such choices are left to the designer at the time this teaching is taken and applied to the design of a tool for accomplishment of a specific task or procedure. For instance, the choice of a wide applicator 40 with a blunt tip will create a large epithelial pocket, for example, for installing a large contact lens in that pocket.

[00101] When the cross-sectional profile of the edge is generally wedge-shaped, the angle of the edge profile may also vary over a reasonable range. For example, in FIG. 5B, the edge is shown having an angle of 20° from the horizontal (70° from the vertical). In one version, the edge profile ranges from 5° to greater than 45°. The angle may be constant over the cross-sectional profile or may vary. For example, in one version, the portion of the edge closest to the bottom surface may be about 20°, while the angle decreases as the edge approaches the upper surface. The angle may be varied to decrease in such a way that there is no visible transition from the edge to the upper surface. The steepness of the edge profile may increase as it approaches the upper surface. The transition between the edge region and the lower and upper surface may be blunt (e.g. smooth), or sharp (e.g. angular).

[00102] Functionally, the edge (in this variation and in the others described herein) may be considered as having an appropriate bluntness when it is able to separate the epithelium from the cornea and produce a delaminated epithelial layer without any (or only insubstantial) corneal tissue attached. In some instances, dealing mostly with the specific physiology of a particular eye, e.g., the presence of scarred sites, the resulting delaminated epithelial layer may have only an insignificant amount of corneal tissue attached. Ideally, the delaminated epithelium has no corneal tissue attached.

[00103] The size and shape of the edge region (e.g. as shown in FIG. 5A, 42) may also vary. For example, the size and shape of the edge may be chosen based on the intended use of the applicator and the size of the flap or pocket desired. In FIG. 5A, the edge region is shown as a semi-circle. Virtually any shape may be used that is capable of achieving the purposes described herein. For example, the edge region may be shovel-shaped, heart-shaped, rectangular, etc. or may simply be flat. The size of edge region (e.g. width) may also vary. Finally, although the edge regions in most of the figures are shown as substantially flat, the edge region may be shaped, for example, to better conform to the slight curvature of the cornea. Other examples of edge region shapes that may be used for the inserter described herein are included in US patent application 10/346,664 (filed 1/17/2003) and US provisional application 60/505,219 (filed 9/22/2003), which are hereby incorporated by reference in their entirety.

[00104] Although the inserter may be shown or described as flat or planar, these terms should be understood to specifically include shapes having a curvature in one axis (e.g. side to side) and in another axis (e.g. front to back) as appropriate to ease the mechanical separation of the epithelium from the corneal surface.

[00105] The edge of the inserter may penetrate the epithelium with or without additional preparation or manipulation of the surface of the epithelium. For example, the epithelium may be scored or otherwise disrupted (e.g. punctured, torn, etc.) before the applicator is used. Generally, the applicator may be used on an initially intact epithelium.

[00106] The edge of the inserter may be made of any material sufficient to withstand the force applied by the edge as it delaminates the epithelial layer from the cornea. Specifically, the edge region may be made of a metal, ceramic, or polymer, and may also be coated with another similar or different material. The materials and coatings may be chosen to enhance the ability of the edge to delaminate the epithelium from the cornea without damaging either the cornea or the epithelial cells. For example, the edge may be made of stainless steel that has been polished (e.g. electropolished) or coated. The edge material may also be made of the same material as the shaft region of the applicator, or it may be made from a different material. Applicators intended for use with living tissue are preferably made of a sterilizable material. The edge may also include a material which incorporates therapeutic properties (e.g. medicaments, growth factors, etc.) to assist the healing process, reduce pain, or to help the cornea in accepting

the optical implant. For example, the edge region (or any region of the applicator) may be configured to release a medicament from a polymeric matrix while in contact with the eye.

[00107] In one version of the applicator, the delaminating edge comprises at least a region of the ocular device to be implanted. For example, the edge may be part of a lens made from a relatively stiff material, or a hydrophilic lens which is not yet fully hydrated. The lens is held by the ocular device holder and at least of region of the lens projects from the applicator and is used to delaminate the epithelial layer from the corneal surface. The lens is released from the applicator and secured into place after delaminating and positioning the lens above the corneal stroma. The applicator is then removed, leaving the lens in place (and re-hydrating the lens, if necessary).

[00108] The top surface 44 and the bottom surface 46 (including the shaft region 64) of the applicator 40 may also affect applicator performance. Top 44 of the applicator contacts the newly delaminated corneal epithelium as the applicator is used. The surface properties of the top of the applicator may be adapted to reduce friction between the applicator and the delaminated corneal epithelial layer. For example, the top of the applicator may be made smooth by polishing and also by at least partially coating it with a material that reduces friction (e.g. a biocompatible lubricant).

[00109] The top region 44 may also comprise a material having a low coefficient of friction with respect to the epithelial layer. Biocompatible lubricants such as Silicones or hyaluronic acids may be used.

[00110] Suitable polymeric materials having a low coefficient of friction include polyethylene, polypropylene, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyurethanes, polyimides, polyamides (such as the Nylons), polyethylene terephthalate (PET), and their mixtures and copolymers. Particularly lubricious polymers include polysulfones, polyxyxylene (e.g., PARALENE), fluoropolymers such as polytetrafluoroethylene (PTFE or TFE), ethylene-chlorofluoroethylene (ECTFE), fluorinated ethylene propylene (FEP), polychlorotrifluoroethylene (PCTFE), polyvinylfluoride (PVF), polyvinylidenefluoride (PVDF), their mixtures, alloys, copolymers, block copolymers, etc. or the like.

[00111] Suitable hydrophilic polymers having a low coefficient of friction include those made from monomers such as ethylene oxide and its higher homologs; 2-vinyl pyridine; N-vinylpyrrolidone; polyethylene glycol acrylates such as mono-alkoxy

polyethylene glycol mono(meth)acrylates, including mono-methoxy triethylene glycol mono (meth)acrylate, mono-methoxy tetraethylene glycol mono (meth)acrylate, polyethylene glycol mono (meth)acrylate; other hydrophilic acrylates such as 2-hydroxyethylmethacrylate, glycerylmethacrylate; acrylic acid and its salts; acrylamide and acrylonitrile; acrylamidomethylpropane sulfonic acid and its salts cellulose, cellulose derivatives such as methyl cellulose ethyl cellulose, carboxymethyl cellulose, cyanoethyl cellulose, cellulose acetate, polysaccharides such as amylose, pectin, amylopectin, alginic acid, and cross-linked heparin; maleic anhydride; aldehydes. These monomers may be formed into homopolymers or block or random copolymers. The use of oligomers of these monomers in coating the device for further polymerization is also an alternative.

[00112] Other suitable lubricious materials include inorganic materials such as diamond, carbon nitride, silicon carbide, diamond-like carbon (DLC), and various other vapor-deposited or pyrolytic carbon films.

[00113] In general, the applicator may also include incorporated therapeutic materials (such as medicaments, etc), for example, to be released during use. All of the applicator, or portions of the applicator may be made of a material having therapeutic properties, or may be coated with (or infused with) a material having therapeutic properties.

[00114] Friction between the top of the applicator and the delaminated epithelium may also be reduced by decreasing the overall bulk, volume, or size of the surface area which contacts the delaminated epithelium. FIGS. 6A and 6B show an applicator in which the edge comprises a ring 121. In this version, friction is reduced because the surface area of the top of the applicator 100 has been reduced due to the presence of the opening 123.

[00115] FIGS. 6A and 6B also show an attachment site 65 by which the applicator may be connected to an applicator mount. Applicator 40 may be attached to an applicator mount at the end of the applicator furthest from the delaminating edge of the applicator. In this version, a driver is connected to the attachment site 65 on the applicator. The driver is configured to oscillate either the entire applicator or predominantly the edge region of the applicator.

[00116] The ocular device applicator also includes an ocular device holder ("the holder") to hold an implantable ocular device. FIG. 7A shows a version of an applicator

holder in which the ocular device resides in a recess in the bottom surface of the applicator 42. In general, the holder releasably secures an ocular device on (or in) the applicator. The holder releases a secured ocular device once the applicator has sufficiently separated the epithelium from the cornea so that the ocular device fits into the delaminated region.

[00117] In similar fashion to the arrangement found in FIGS. 1-4B, the FIG. 7A ocular device holder conforms to at least a portion of a region of the ocular device. The ocular device holder may conform to at least one outer surface of the ocular device or it may completely enclose the ocular device. The device shown in FIG. 7A is configured so that a lens would fit into the cavity formed by the holder region 60 so that the lens does not project beyond the plane of the bottom side 46. In the devices shown in FIGS.5A-5C and 6A-6C, the ocular device holder 60 forms a cavity in the bottom of the applicator into which the ocular device fits. The holder is shown to be near the delaminating edge of the applicator 42, and the holder is surrounded by this edge on at least three sides. The holder need not be a recess in the bottom of the applicator. The holder may project from the bottom surface of the applicator. Placing the holder on or near the bottom of the applicator allows the applicator to deposit the ocular device after delaminating an appropriately-sized region of the cornea.

[00118] The holder or holding region may comprise cavities in both the top and the bottom of the applicator (for example, see FIGS. 6A, 6B, and 6C). In particular, FIG. 6C shows a lens 47 situated within the holding region beneath the blade 42 but extending through the blade 42 and extending from the top of the ring 61.

[00119] The ocular device holder holds the ocular device before and during delamination, and releases the ocular device after delamination is substantially complete. The ocular device may be held and/or released from the holder and by applying force to ocular device, or by using a releasable adhesive, or by a combination of both.

[00120] As discussed above, the ocular device may be held in the ocular device holder by applying a vacuum. One or more channels 67 connect to the holder as shown in FIG. 7A. A restraining force may be applied to an ocular device in the holder through this channel 67. A negative force may be applied to secure the ocular device in the holder (e.g. by drawing a vacuum) and a positive force may be applied to release the ocular device from the holder. For example, air pressure (or any other gas) may be

applied through the channel to release the ocular device. Fluid pressure (e.g. water or saline pushed through the channel) may be applied to release the ocular device. Any fluid could be used to controllably hold and release the ocular lens in the applicator. Further, the channel may be used to apply other useful substances (e.g. liquids such as saline, medicaments, etc.) to the eye and may be used to provide a cooling fluid.

[00121] The ocular device may be held in the holder by a releasable adhesive. In particular, a dissolvable adhesive may be used. For example, in one version a water-soluble material secures the ocular device in the holder until it is ready to be released after insertion. Water or saline or other fluid may then be applied to dissolve the adhesive. Examples of water-soluble materials include, but are not limited to: polymers such as polyvinylalcohol (PVA), biopolymers such as hyaluronic acid (HA), and polysaccharides. Application of a fluid that releases the adhesive (e.g., saline, water, or other beneficial fluid) causes the adhesive to dissolve or otherwise release, allowing implantation of the ocular device. Such a solution may be applied locally (e.g. through a channel 67) or over a larger area of the cornea.

[00122] FIGS. 8A, 8B, and 8C show a spatula-like applicator similar to that shown in FIGS. 7A and 7B. In FIG. 8B, a channel 67 connects the ocular device holder region 60 at the more distal end to a vacuum source or to a source of air or liquid (not shown) that are regulated to apply force to hold or to release an ocular device in the holder 60. The inner portion of the holder 60 includes additional channels 69 to distribute the force over an ocular device held in the ocular device holder 60. The channel 67 shown in FIG. 8B is depicted to be open, but is typically enclosed to allow pressure to be transferred to the holder.

[00123] FIG. 8C shows the holder 60 retaining an ocular device 71 (a lens). The channel 67 connected to the holder has been sealed with an external covering (e.g. tape) 73. The channel may be incorporated within the inside of the applicator.

[00124] In operation, the applicator may be attached to an applicator mount, handle, or system configured variously to assist the user in moving the blade or applicator across the cornea and in depositing the chosen implant at the desired site.

[00125] The applicator may be fabricated either in separate parts (e.g. the edge, the holder, etc.) and assembled, or it may be fabricated as a single piece. For example, the applicator may be injection molded or micro-stamped into shape. The size of the applicator is chosen by the designer and depends in large part upon the intended use of

the applicator centering mostly upon the device to be. The dimensions of the applicator are typically selected so that the edge has a thickness similar to the thickness of the basal cell layer, e.g., about 1/2 mil to 3.5 mils. (0.0005 to 0.0035"), but often about 1.0 mil to 3.0 mils (0.001 to 0.003"). For example, the edge of the applicator may have a thickness around 2.0 mils.

[00126] FIG. 9A shows a top view of the described dissector 80. As will be discussed later, dissector 80 – also denominated herein as a blunt blade or separator – comprises a blade body 82 with a blunt body edge 84 surrounding a substantial portion of the blade body 82. This variation of the described dissector 80 includes a blunt edge 84 that is generally curved in shape. It may be elliptical or a portion of a circular shape. Since the blade body 82 is often vibrated side-to-side during the separation step, some portion of the side of the blade edge 84 may be configured to separate epithelium from the cornea.

[00127] In this variation of the blade 80, the blade body 82 includes a large opening 86. The opening 86 is positioned in the blade body 82 so that as it passes sub-epithelially across the cornea, the dissector incurs a much smaller level of friction between the blade body 82 and the epithelium than would a blade not having such an opening. The diameter of the opening, where the opening 86 is circular, may have a diameter that is as much as 75-85% of the diameter 88 of the blade edge 84. The opening provides a benefit even when as small as 10-15% of the blade diameter 88.

[00128] The variation of the blade body 82 discussed in FIGS. 9A-9C includes a portion configured to attach to a vibrator or oscillator. Such portion may include an extension 90 or neck and openings 91 for fasteners. Other fastening arrangements may be used. The blade body 82 may be alternatively be integrated into the de-epithelialization assembly, as discussed below.

[00129] FIG. 9B1 provides a cross-sectional side view of a variation with the blade body 82 having a cornea side 92 and an epithelium side 94. In this variation, the cornea side 92 is concave, perhaps having a shape conforming to or similar to the shape of the treated cornea.

[00130] FIG. 9B2 shows a cross-sectional side view of another variation of the cornea side 92 where that cornea side 92 is substantially flat. Suitable curvature for the cornea side 96 extends in value between the radius of the cornea to the infinite theoretical radius formed by a straight line.

[00131] FIG. 9C shows a cross-sectional front view of the blade body 82 showing the blunt edges 84 and the central opening 86.

[00132] FIGS. 10A-10D show another variation of the dissector or blunt blade 98 having a flat section 100 located on the epithelium side 102. The flat area or section 100 serves as a friction reducing region similar in function to the opening 86 in the blade body 82 in FIG. 9A.

[00133] FIG. 10B shows a side section of blunt blade 98 having flat section 100. The blade edge 104 is positioned similarly to blunt edge 82 in FIG. 9A.

[00134] FIG. 10C shows an end section of the blunt separator blade 98 showing the flat section 100.

[00135] Finally, FIG. 10D shows a close-up, cross-section of the junction of the flat region 100 of the epithelian side 102 and curvature of the cornea side 98.

[00136] Other designs for lowering the incident friction between the dissector blade and the separated epithelium are suitable. For instance, the epithelium side of the blade may be fitted with physical structures designed to lower friction.

[00137] FIGS. 11A – 11D show another variation of the blade 60 or blunt dissector blade having a feature including a physical friction-reducing design. The depicted blade variation 60 includes a blunt dissector edge 132, of the same general type as shown in many of the other drawings and described in the specification, but further includes a friction reducing region 134 having a number of long ridge-like structures 136 intended to have very small contact patches with the epithelium as it slides longitudinally along the epithelium face 138 of the blade 60. In general, the depicted blade 60 is shown not to have openings through blade body 140 although, certainly, inclusion of one or more openings amongst the ridge structures 136 would be permitted.

[00138] FIG. 11B again shows cutting blade 60. This view is a cross sectional view of the section noted in FIG. 11A. It shows the ridges 136 extending from the epithelium side 138 of the blade body 140. In general, it may be seen from FIG. 11B, that the blade body 140 is or may be flattened in the region of ridges 136.

[00139] FIG. 11C shows a region 142 circled in FIG. 11B. The FIG. 11C also shows that the cornea side 144 of the blade is, in this depicted variation, somewhat concave.

[00140] FIG. 11D provides an end view, cross section of the magnified region 142 shown in FIG. 11C.

[00141] FIG. 11D again shows cornea side 144, epithelium side 138, and smooth ridges 136.

[00142] The blade edges of the described blade (and the other blade variations described herein when those blades are used solely for epithelial delamination) may alternatively be described as "epithelial dissector edges" and those edges may be characterized as being "blunt". Expanding upon the discussion above, by the term "blunt" is meant that the edges are functionally not capable of cutting into the cornea, or Bowman's Membrane, as it is passed axially (with respect to the blade access) at an angle to the contact surface of the cornea of 25° or less. At the same time, however, the blade edge is capable of penetrating and passing through the epithelium layer and separating that epithelium tissue into a separated or lifted epithelial tissue member as that blade is passed over the cornea. This separation would generally take place at the lamina lucida unless the structure of the eye includes some aberrational feature. For instance, scar tissue may cause the dissector to take a modestly different or interrupted passage below the epithelium in certain instances.

[00143] The specific form or profile of this blade is not material to the physical friction reducing feature of the blunt blade described above.

[00144] However, we have found that using an electropolishing step on a blade edge specifically, to form the blade edge rather than just to polish it, that otherwise may well have been sufficiently sharp to cut into corneal tissue, e.g. the Bowman's Membrane, produces a blade edge that is quite useful. Electropolishing is the electrolytic removal of metal in a highly ionic solution using an electrical current. It may be thought of as "reverse electroplating." Electropolishing often produces a microscopically smooth and reflective surface. The current densities found at sharper points or edges in any electropolishing process preferentially remove or polish those sites, burrs, or edges, and when used with the described blades will blunt the blade blanks used to produce the blunt blades and provide a consistent edge that functionally will separate epithelium tissue from the cornea without cutting corneal tissue. The temperatures used in electropolishing blade blanks used for the described blunt blades are well known, and are easily found in the public descriptions of the process. The temperature may be slightly elevated from room temperature, e.g., 110° - 160° Fahrenheit. The voltage applied to stainless steel metallic blade blanks might typically be in the range of 6-30 volts although the lower voltage end of the range is often used. Amperage may be

between 5 and 30 amps per square foot of a blank blade area. Acidic additives, e.g., sulfuric acid or phosphoric acid, may be employed.

[00145] FIG. 12A shows a cross section of an edge 150 of a typical stainless steel blade blank 152. Blade edge 150 is shown to be fairly sharp and, in this instance, is of sharpness suitable for cutting corneal tissue. The various arrows 154 shown in FIG. 12A are schematic indicators of the current density of the process. The current density 154 is shown to be higher at the blade blank edge 150 and lower elsewhere. The sharpness of edge 150 is preferentially removed during this process to produce the blunted edge 156 seen in FIG. 12B. There are other blade edges that are suitable for reaching the functional result specified here. Some of the other shapes will be discussed below.

[00146] The various cutting, inserter, and dissector blades may be used for a variety of tasks as otherwise discussed above. In some instances, it may be desirable to provide fluid to the epithelium or to the cornea during the process of separating the epithelium from the cornea. Cooled fluid such as a saline solution, is often helpful in providing predictable viability to the produced separated epithelial tissue member.

[00147] FIG 13A shows a top view of a cutting blade 160 having a groove for fluid 162 situated on the epithelium side 164 of the blade 160. FIG. 13B shows a cross section of the FIG. 13A blade with a groove 166. The exterior groove 166 is shown to be exterior, but may also be an enclosed passageway having one or more openings placed to be beneath (or opening to) the epithelium or onto the cornea and allowing passage of the fluid during the separation of step or the blade removal or at any period in between.

[00148] FIG. 14A shows a similar variation 168 having a passageway 170, in this case, as shown in FIG. 14B where the passageway or channel 170 is positioned on the cornea side 172 of the blunt blade 160.

[00149] FIGS. 15A – 15D show a variety of "blunt" blade edges that are schematically suitable for use in the described cutting blade. FIG. 15A shows a blade 180 having an edge 182 wherein the edge has a slight convex profile 184 on the corneal side. FIG. 15B shows a blunt blade 180 having a shape on the corneal side 186 that is slightly concave in shape. FIG. 15C shows a blunt blade having a cornea- side bead or ridge 188. FIG. 15D shows a blade 180 having substantially flat cornea side 190.

[00150] In the variations of the cutter or dissector blades that are used to produce epithelial tissue members forming pockets that are enclosed pockets, or at least partially enclosed, in that the edge of the member is of a place and type that cannot form a hinge or other rotation point about the corneal surface, e.g., forms the edge of a pocket, may have separating edge of the side of, or at least off of the axis of the blade.

[00151] Since the blade bodies may oscillate in a side-to-side motion, or other motion that is not strictly axial in nature, the blades' separating edges may have a "separating shape" that subsects a significant portion of the leading edge of the blade. For instance, FIG. 16A shows a blade 200 having a blade edge 202 that subsects an angle 204 that is about 180°. FIG. 16B shows another variation of the blade 206 in which the leading edge 208 includes a separation surface that subsects an angle 210 of 210° to 225°. FIG. 16C shows a blade body having a separating edge 214 that subsects perhaps 270°-280° 216 of the blade body 212. Similar concepts may be applied to blades having shapes other than partially circular.

[00152] The blunt blades may be made from a variety of suitable materials. Although various stainless steel and spring steels are very suitable as blade materials, polymeric materials such as polymethylmethacrylate (PMMA) and polycarbonates are suitable for chosen designs or variations of the described blunt blade.

[00153] As was mentioned above, the described epithelial delaminator blade may employ lubricious material on one or more surfaces. The lubricious material may be of several different forms, variously permanent (i.e., lasting at a substantially constant thickness throughout the epithelial delamination step), temporary (i.e., a solid, gel, or particulate material, perhaps suspended in a fluid that decreases in volume or thickness during the epithelial delamination step), reactive (i.e., a hydrogel or other polymeric material reacting with water to form a slippery material during or just prior to the epithelial delamination step), and fluid lubricant (i.e., a fluid introduced with the delaminator). The delaminator may, during the procedure, be completely covered with the lubricious material, or may be partially covered with the lubricious material. In particular, the portion of the delaminator blade that contacts the epithelium during the epithelial delamination may at least partially comprise a lubricious material while the cornea side is less lubricious by comparison.

[00154] FIGS. 17A-17D show a variation 240 of the delaminator cutting blade 10 shown in FIGS. 1-4 above. This variation is also useful in simultaneously placing

implanted lenses (or other onlay or implant). The figures also show the subcomponent parts and the carried lens 242.

[00155] FIG. 17A shows, in cross-section, a delaminator 240 and the carried lens 242. The lens 242 is shown in slight separation from the face of the delaminator 240 for clarity of explanation and portrayal. The delaminator 240 shown comprises a domed section 244 and a sealing plate 246. Top and bottom views of the domed section 244 are shown respectively in FIGS. 17B and 17E, the former drawing with the lens 242 removed and the latter with the sealing plate 246 removed. The lens 242 is shown in isolation in top view in FIG. 17C. The sealing plate 246 is shown in isolation in top view in FIG. 17D.

[00156] Returning to the domed section 244 in FIG. 17A, this variation is adapted to carry the lens on the upper surface 248. The upper surface 248 may be formed to at least approximate the undersurface 250 of the lens 242. Passageways 252 of various sizes and positions are shown allowing communication of vacuum from the lower surface 254 to the upper surface 248 and to the lens 242. The vacuum may be used to hold the lens 242 in position until delivery. As is shown with more detail below, the upper surface 248 may include an inset having a ridge 253 to allow the edge of lens 242 to pass more easily across the underside of the epithelium during the entrance portion of the lens insertion procedure. Additionally, the upper surface 248 may include a lubricious covering or coating 253 on at least the surfaces contacting the lens 242 and those surfaces contacting the epithelium during introduction of the delaminator 240 and during its withdrawal after placement of the lens 242. The remainder of the delaminator 240 may also be treated to be lubricious, but we have found such treatment to be of limited added benefit. FIG. 4B above shows the partial lubricious coverage 31 of a very similar variation.

[00157] FIGS. 17A, 17B, and 17E each show a leading edge 262 that has the function of initially penetrating the epithelium and then separating the epithelium from the cornea, the Bowman's layer. Acceptable shapes of the edge, the cross-section and the adjacent ramp, are discussed below and elsewhere herein.

[00158] Again returning to FIG. 17A, the chamber 256 formed between the sealing plate 246 and the underside 254 of domed section 240 may also be used to allow passage of fluid such as saline or water (and medicaments, if desired) to push the lens 242 from the upper surface 248 as a portion of the release step.

[00159] As shown in FIGS. 17F and 17G, the chamber 256 may be separated into a number of independent chambers, if so desired, and accessed by independent passages through the drive leg 260. The independent passages (262, 264) in the drive leg 260 may be placed there by machining, casting, etc. Similarly, the chamber 256 may be separated into independent chambers (266, 268) by a wall or walls 270 projecting upwardly from sealing plate 246. FIGS. 17F and 17G show top and end views of such a variation, a variation having separated flow paths for independent chambers. In this variation, a single meandering wall 270 provides two chambers (266, 268), in this example accessing separate sets of passageways through the domed section. One chamber 268 accesses the outer circle of openings 252 and the central opening 251. The other chamber accesses the other four openings 253 in the domed section 244 shown in FIGS. 17B and 17E. The passageways and chambers may be isolated to permit separate access by, e.g., the vacuum or the saline, to separate passageways 250 in the domed section 244. We have found that such separate access is sometimes desirable. Distributed vacuum at the edge of the lens, provided by numerous, smaller passageways or openings 252 at the edge of domed section 244, appears to help with lens stability during insertion of the inserter/delaminator 240. A large through-passageway or opening 250 at the center of the domed section 244 for passage of water or saline appears to assist in releasing the lens when desired.

[00160] FIG. 17B shows a top view of the domed section 244 of FIG. 17A. The inset edge 253 may be seen, as well as the various open passageways (251, 252, 255).

[00161] FIG. 17C shows a top view of the selected lens 242. The lenses suitable for use with this device are not limited in any way. As discussed above, they may be soft, flexible, or they may be hard lenses as those terms are used in ophthalmology. The lenses may be of hydrophilic or hydrophobic polymers or of their mixtures, block or random copolymers of those materials, composites, multi-layer constructs, and the like.

[00162] FIG. 17D shows the top view of a sealing plate 246.

[00163] FIG. 17E shows a bottom view of the domed section 244 with the sealing plate (246 in FIG. 17D) removed. The rabbet 267 for supporting the edge of the sealing plate 246 may be seen. The various passageways or openings (251, 252, 255) through the domed section 244 may also be seen.

[00164] The various passageways configured to communicate holding vacuum and release fluids to the various open passageways (251, 252, 255) may also be used to pass

cooling fluids to one or more of those various open passageways (251, 252, 255) to cool the epithelium or cornea within the pocket.

[00165] FIGS. 18A-18E show another variation of the delaminator/blade 290, in particular, a domed section 292 and its attendant lens 294. This variation carries the implant lens 294 beneath the domed section 292.

[00166] FIG. 18A shows a side-view cross-section of the delaminator 290, the domed section 292, a sealing plate 306, and its attendant lens 294. The chamber 298 beneath the domed section 292 may be adapted or configured to retain the lens 294 during delivery and to controllably release the lens 294 when the desired deployment site is attained.

[00167] One way to retain the lens 294 within the domed section 292 during delivery is depicted in the bottom view shown in FIG. 18B. Various recesses 300 may be placed in the underside 302 of the domed section 292. The recesses 300 may be connected to a passageway 304 found in the arm 308 beneath the sealing plate 306 for passage of vacuum to the recesses. Those same passageways and recesses may be used to apply fluids such as water or saline to release the lens 294 in FIGS. 18A and 18C).

[00168] FIGS. 18A and 18B show the leading edge 310 of the delaminator 290 that has the function of initially penetrating the epithelium and then separating the epithelium from the cornea, the Bowman's layer. The appropriate shapes of the edge, the cross-section, and the adjacent ramp, are discussed elsewhere.

[00169] FIG. 18C shows a top view of lens 294.

[00170] FIG. 18D shows a top view of domed section 292.

[00171] FIG. 18E shows a partial close-up, cross-section of the epithelial delaminator 290 shown in FIG. 18A. In particular, FIG. 18E shows the presence of a lubricious coating 318 on the upper surface of the delaminator in the regions where the delaminator blade contacts the epithelium during the delaminating procedure.

[00172] Again, each of the various epithelial delaminators discussed herein may be adapted or configured to secure an implant during the implantation and delamination step and to release the implant using the teachings found herein.

[00173] The following figures show a variety of delaminator shapes and placement of lubricious materials and, in some instances, the potential shapes of the formed epithelial regions. In some instances, the delaminators may be configured to include an implant for contemporaneous placement of that implant during the delamination step.

[00174] FIG. 19A shows a top view of a spatula shaped delaminator 340. The delaminator 340 may be oscillated from side-to-side or axially front-to-back and in combinations of the two.

[00175] FIG. 19B shows a side-view cross-section of the delaminator 340 with a substantially flat bottom 342 situated adjacent the eye and cornea during use. The non-cutting leading edge 344 is also seen, as is a rounded top surface 346.

[00176] FIG. 19C shows a front-view cross-section of the delaminator 340 and the sloping, rounded shape of the top surface 346. The top surface 346 is adjacent the epithelium during the step of delaminating the epithelium.

[00177] FIG. 19D shows a partial cross-section of the delaminator 340 and, specifically, the blade substrate 348 with a lubricious layer 350 situated on the side of the delaminator 340 that is adjacent the epithelium during use.

[00178] FIG. 19E shows a partial cross-section of the delaminator 340 with the blade substrate 348 having lubricious layers 350 on both sides of the substrate 348.

[00179] FIG. 20A shows a top view of an epithelial delaminator 360 having an active end that is substantially circular. As was the case with the delaminator shown in FIG. 19A, this variation may be oscillated from side-to-side or axially front-to-back or in combinations of the two movements. The leading edge 362 need be configured having a separating shape only in the marked region 364.

[00180] FIG. 20B shows a side-view cutaway of delaminators 360 with leading edge 364. The shape is seen to be somewhat dome-shaped in the body or substrate 366 of the delaminator 360.

[00181] FIG. 20C shows a cross-section front view of delaminator 360 and the dome-shaped substrate 366.

[00182] FIG. 20D shows a partial cross-section of delaminator 360 and, specifically, the blade substrate 366. The lubricious layer 368 is shown situated on the side or region of the delaminator 360 adjacent the epithelium during use.

[00183] FIG. 20E shows a partial cross-section of delaminator 360 having a lubricious layer 368 on both sides of delaminator substrate 366.

[00184] FIG. 21A shows a top view of a delaminator 380 having a leading portion 382 in the nature of a prow. This delaminator may be used to produce the substantially hinged epithelial flat, not the epithelial pocket discussed elsewhere herein. Delaminator 380 may be oscillated from side-to-side or axially front-to-back during use but is

typically used only with a front-to-back oscillation. FIG. 21B shows a side view of the delaminator 380 with a leading edge 382.

[00185] FIG. 21C shows a partial side-view, cross-section of delaminator 380 having a blade substrate 384 and a layer of lubricious material 386 only on those portions tending to contact the epithelium during the delamination step.

[00186] FIG. 21D shows a delaminator 380 with a substrate 384 and a lubricious coating 386 on all surfaces contacting the eye during use.

[00187] FIG. 22A shows a top view of a delaminator 390 that is somewhat spatula-shaped but includes a dome shaped region 392 on its top side and, as will be seen in FIG. 22B, a concave shaped portion 394 on its bottom side 396. The epithelial delaminator dome 392 includes a leading edge 396 having an edge configured to separate the epithelium from the Bowman's layer without cutting the cornea or leaving substantial epithelial tissue on the cornea or corneal tissue on the underside of the epithelium.

[00188] FIG. 22B shows a front cross-sectional view of delaminator 390 showing both the dome 392 and the concave region 394.

[00189] FIG. 22C shows a side-view of delaminator 390 and the presence of the dome 392.

[00190] FIG. 22D shows a partial, side-view, cross-sectional view of the delaminator 390 with a dome 392 and the concave region 394 on the bottom side 396.

[00191] FIG. 22E shows a partial cross-sectional view of delaminator 390 blade substrate 398 and a lubricious layer 400 on the dome-shaped region. The dome-shaped region of delaminator 390 contacts the underside of the epithelium during the delamination step.

[00192] FIG. 22F shows a partial, cross-sectional, side-view of delaminator 390 and, in this instance, shows a lubricious layer 400 on both sides of blade substrate 398.

[00193] FIG. 23A shows a simple wire whip delaminator element 401 that is oscillated back and forth as shown in FIG. 23B to form a region of separated epithelium.

[00194] FIG. 23C shows one shape of a separated epithelial region 402 that may be produced by varying the "whip point" position 404 as the wire is moved axially beneath the epithelium 406.

[00195] FIG. 23D shows the substrate wire 408 and the partial lubricious coating 410 on the sections of wire acting as the delaminating element 401 and those regions that contact the cornea and the epithelium.

[00196] FIG. 23E shows the delaminating wire element 401 with a wire substrate 408 and the lubricious covering 410 covering substantially all of the substrate 408.

[00197] FIG. 23F shows the delaminating wire elements 401 with a substrate 408 and a lubricious coating 410 covering the regions of the substrate wire 408 that contact the epithelium.

[00198] FIG. 24A shows an epithelial delaminator 411 having a substantially oval cross-sectional area. The side-to-side dimension of the oval in this variation would typically be substantially smaller, e.g., less than 10% of, the diameter of the epithelium of the eye for which is separated epithelial region is desired.

[00199] FIG. 24B shows a limited rotation motion 412 for the epithelial delaminator element 411.

[00200] FIG. 24C shows a side-to-side movement 414 for the epithelial delaminator element 411.

[00201] FIG. 24D shows a combination motion for the epithelial delaminating member 411 where a side-to-side rotational motion is combined with an axial motion to produce a lifted epithelial region having a connected edge 416 and an opening 418 to beneath the epithelium. This configuration may be used to produce a pocket with a large opening.

[00202] FIG. 24E shows epithelial pocket having an attached edge 420 and a small opening 422 made by introducing delaminator 411 beneath the epithelium and both rotating it about a pivot point near the mouth 422 and withdrawing the delaminator 411 at the extreme angles of motion to form the region shown there. This combination of rotatory and axial movement of the delaminator 411 is useful in producing a pocket having a small opening and a large and closed region beneath the epithelium.

[00203] FIG. 24F depicts a cross-section of delaminating element 411 with the blade substrate 430 and a coating of lubricious material 432 on the face of the delaminating element that is in contact with the epithelium during the delaminating step.

[00204] FIG. 24G shows a cross-section of the delaminating element 411 with a substrate 430 and a lubricious coating 432 covering all of the surfaces of the delaminating element 411 that contact the eye.

[00205] The delaminator/cutter device described with respect to FIGS. 23A-24G is not in a physical form that is readily adaptable to carrying an implant during the epithelial delamination step. However, they are especially suitable for providing epithelial pockets with relatively small openings and for use with implants that may be folded for introduction into the pocket and for implants that are formed in situ and introduction of the reactants or forms or the like. In such uses, the folded lens or reactant materials may be transported on a different system component that may or may not be contemporaneously introduced into the epithelial pocket.

[00206] Often, the delaminator is used to insert an ocular device beneath a substantially intact sheet of the epithelium, that is to say: the portion of the epithelium that passes to the anterior side of the dissector is continuous. However, the delaminator may be used in less elegant ways. For instance, the delaminator may be used to move or to remove selected portions of that membrane. Indeed, when this device is used in conjunction with a LASEK procedure, the epithelium may be removed in the form of a soft flap allowing for ease of epithelial replacement or re-positioning once any corneal laser remodeling is completed.

[00207] In some instances it may be desirable to also apply heat to the anterior surface of the eye to enhance the mechanical epithelial delamination or to apply cooling fluids to the device and to the epithelium to enhance the viability of the epithelium after the conclusion of the procedure.

[00208] This described blunt dissector blade may be used in a device having only a handle, that is to say, without any mechanical vibration or drivers for advancing the blade across the cornea. More often, as shown in FIGS. 25A and 25B, the blunt blade dissector 450 is used in conjunction with a vibrator 452 that is used to vibrate the blade 450 as depicted by arrows 454.

[00209] Additionally, the handle 452 may employ, in addition to a vibration driver, a driver allowing axial movement 456 of the blunt blade 450 either by manual movement of the blunt blade 454, as by pushing with a thumb or, handle 452 may employ and electrical or motor driven driver to move the blade, with vibration 454, axially across the cornea. This axial movement 456 may, for instance, take place with the use of alignment rails 458 to provide ease of passage across the cornea.

[00210] The schematic procedure for providing an epithelial tissue member using a blunt blade such as is described here is shown in FIGS. 26A – 26D. FIG. 26A shows an

eye 460 having a cornea 462. A blunt blade 464 having both side to side oscillation 466 and axial movement 468 approaches eye 460.

[00211] FIG. 26B shows the entry of blade 464, still oscillating 466, by penetrating the epithelial layer and forming an opening 468.

[00212] FIG. 26C shows movement of the blade 464 has stopped both axially and, perhaps, oscillatory. Blade 464 sits inside an epithelial tissue member 470 having an opening 468. In this instance, epithelial tissue member 470 is in the general form of a circular pocket. The described devices are best at making epithelial tissue members that retain some portion of the epithelial tissue member 470 attached to the cornea. In some instances, the epithelial tissue member 470 may have attachment regions that are such that they will allow the epithelium to form in the shape of, e.g., a flag, and rotate away from or otherwise move from the vicinity of the front of the cornea.

[00213] In any case, FIG. 26D shows a removal of blade 464 from eye 460 leaving an epithelial tissue member 470 and an opening 468 to allow entry beneath epithelial member 470 for some further treatment of the eye, e.g., a LASEK procedure other laser treatment procedure, or placement of an ocular lens. In each instance, the epithelial tissue member may remain on the ocular surface above the results of any treatment, be the treatment laser induced or implant in nature. Replacement of the epithelial tissue member above the site of a mechanical or surgical eye treatment or other treatment of any kind is also appropriate.

[00214] Similarly, the described blades may be treated or coated with ephemeral, temporary, or permanent coatings further to improve the friction improvement capabilities of the described blunt blades. The coatings may be those listed above.

[00215] The described mechanical epithelial delaminators may also be considered to be blunt dissectors. Blunt dissectors have non-cutting surfaces that are appropriate for placement between the epithelium and the collagenous stromal tissue. As used herein, the term "non-cutting" means that the blunt dissector does not have the ability to incise into the stroma of the cornea when used with normal force. I believe that my blunt dissectors separate the epithelium from the stromal layers of the cornea in the basal membrane zone at the natural point of weakest attachment, i.e., the lamina lucida. The so-separated epithelium does not contain substantial amounts of corneal stromal tissue, or for purposes of this invention, does not contain any more than an insubstantial amount of the stromal tissue when the procedure is practiced on "normal" eyes (those

having no artifacts due to injury or to disease). The so-separated epithelium does not contain Collagen Type I or Type III as may be found in the stromal tissues.

[00216] Although the procedure here may be used to dissect a substantially intact sheet of the epithelium, i.e., the portion of the epithelium that passes to the anterior side of the dissector is continuous, the device may be used to make other epithelial tissue structures. For instance, the dissector may be used to remove but selected portions of that membrane. Indeed, when this device is used in conjunction with a LASEK procedure, the epithelium may be separated in the form of a soft flap allowing for ease of replacement or re-positioning once any corneal laser remodeling is completed. This dissector may be used to form an epithelial pocket.

[00217] The epithelial delaminating methods herein described may also be used in conjunction with corneal reshaping procedures or procedures that involve placement of ocular lens devices on the surface of the eye. Specifically, the disclosed procedure may be used to prepare an epithelial pocket or a flap, often with an attached hinge. A suitable ocular lens may then be placed on the stromal surface and the epithelial flap replaced over the lens. One such suitable ocular lens device to be used with the present invention is described in U.S. Pat. No. 6,544,286 which is herein incorporated by reference in its entirety.

[00218] Similarly, a corneal reshaping procedure may be performed and the corneal flap replaced.

[00219] The structure and physiologic properties for my invention, as well as certain of the benefits particular to the specific variations of this epithelial delaminating device, have been described. This manner of describing the invention should not, however, be taken as limiting the scope of the invention in any way.

WE CLAIM AS OUR INVENTION:

1. A low friction dissector blade configured to form an epithelial tissue member at least partially attached to a cornea, by cutting the epithelium and separating the epithelium from an eye having epithelium attached to a cornea, but configured not to cut the cornea, during oscillatory, transverse passage of the blade across the eye to form the epithelial tissue member, the blade comprising: a blade body with at least one non-corneal-cutting, epithelial tissue-separating blunt edge, a epithelial surface configured to pass adjacent the epithelium during the transverse passage and a corneal surface configured to pass adjacent the de-epithelialized cornea during the transverse passage, and a lubricious covering on at least a portion of that epithelial surface but not on the corneal surface.

2. The dissector blade of claim 1 wherein the lubricious covering comprises a liquid lubricant comprises a member selected from the silicones and hyaluronic acid.

3. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of polyethylene, polypropylene, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyurethanes, polyimides, polyamides, polyethylene terephthalate (PET), and their mixtures and copolymers.

4. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of polysulfones, fluoropolymers, and their mixtures, alloys, random copolymers, and block copolymers.

5. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of polytetrafluoroethylene (PTFE or TFE), ethylene-chlorofluoroethylene (ECTFE), fluorinated ethylene propylene (FEP), polychlorotrifluoroethylene (PCTFE), polyvinylfluoride (PVF), polyvinylidenefluoride (PVDF), their mixtures, alloys, random copolymers, and block copolymers.

6. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of hydrophilic polymers made from monomers including ethylene oxide and its higher homologs; 2-vinyl pyridine; N-vinylpyrrolidone; polyethylene glycol acrylates, mono-alkoxy polyethylene glycol mono(meth)acrylates, acrylic acid and its salts; acrylamide and acrylonitrile;

acrylamidomethylpropane sulfonic acid and its salts, cellulose, cellulose derivatives, polysaccharides, maleic anhydride; and aldehydes.

7. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of hydrophilic polymers made from monomers including mono-methoxy triethylene glycol mono (meth)acrylate, mono-methoxy tetraethylene glycol mono (meth)acrylate, and polyethylene glycol mono (meth)acrylate, 2-hydroxyethylmethacrylate, and glycerylmethacrylate.

8. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of hydrophilic polymers made from monomers including methyl cellulose ethyl cellulose, carboxymethyl cellulose, cyanoethyl cellulose, and cellulose acetate.

9. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of hydrophilic polymers made from monomers including such as amylose, pectin, amylopectin, alginic acid, and cross-linked heparin.

10. The dissector blade of claim 1 wherein the lubricious covering comprises one or more members selected from the group consisting of diamond, carbon nitride, silicon carbide, diamond-like carbon (DLC), and vapor-deposited or pyrolytic carbon films.

11. The blade of claim 1 wherein the blunt edge comprises a shape formed by electropolishing a sharp edge capable of cutting corneal tissue.

12. The blade of claim 1 further comprising a vibrator driver.

13. The blade of claim 1 further comprising a transverse movement driver.

14. The blade of claim 1 further configured to retain an ocular implant during the transverse passage.

15. The blade of claim 1 further comprising coolant pathways.

16. A low friction dissector blade configured to form an epithelial tissue member at least partially attached to a cornea, by cutting the epithelium and separating the epithelium from an eye having epithelium attached to a cornea, but configured not to cut the cornea, during oscillatory, transverse passage of the blade across the eye to form the epithelial tissue member, the blade comprising: a blade body with at least one non-corneal-cutting, epithelial tissue-separating blunt edge, and an opening through the blade body.

17. The blade of claim 16 wherein the blade body comprises a cornea side and an epithelium side.

18. The blade of claim 17 wherein the blunt edge comprises a shape formed by electropolishing a sharp edge capable of cutting corneal tissue.

19. The blade of claim 17 further comprising a lubricious coating applied to at least a portion of the blade body epithelium side.

20. The blade of claim 16 further comprising coolant pathways.

21. A dissector blade configured to form an epithelial tissue member at least partially attached to a cornea, by cutting the epithelium and separating the epithelium from an eye having epithelium attached to a cornea, but configured not to cut the cornea, during oscillatory, transverse passage of the blade across the eye to form the epithelial tissue member, the blade comprising: a blade body with at least one non-corneal-cutting, epithelial tissue-separating blunt edge, the blunt edge having a shape formed by electropolishing a sharp edge capable of cutting corneal tissue.

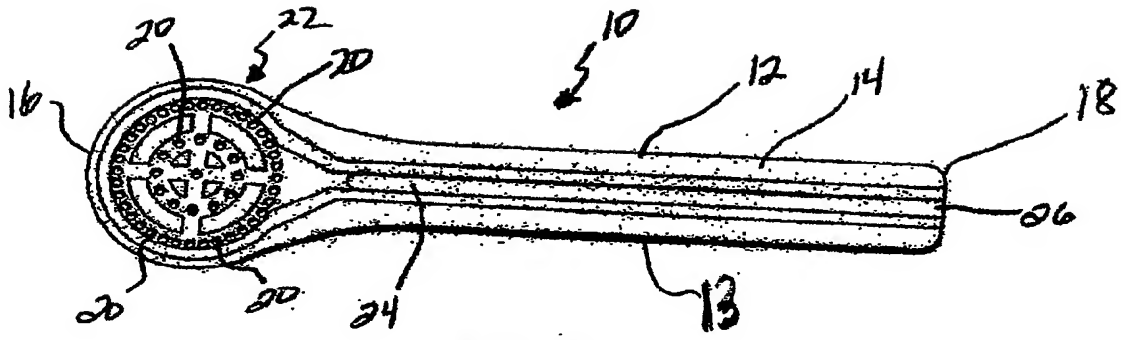


FIG. 1

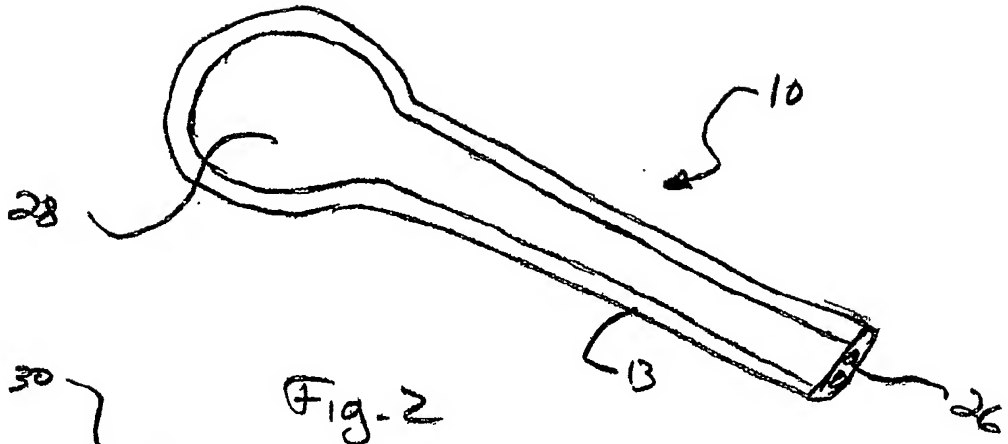


Fig. 2

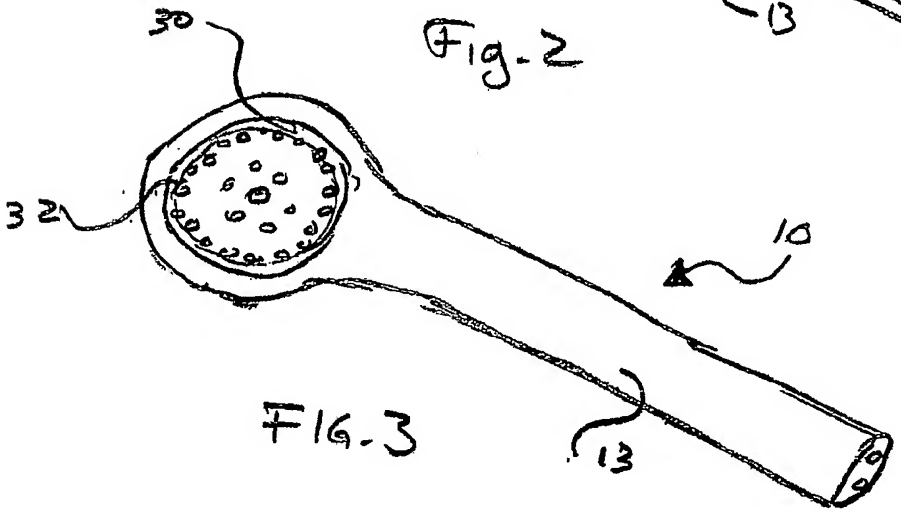


Fig. 3

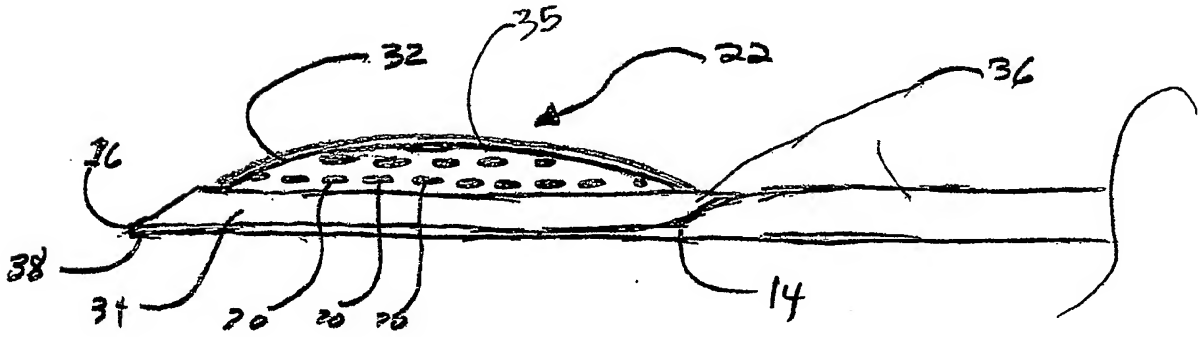


Fig. 4A

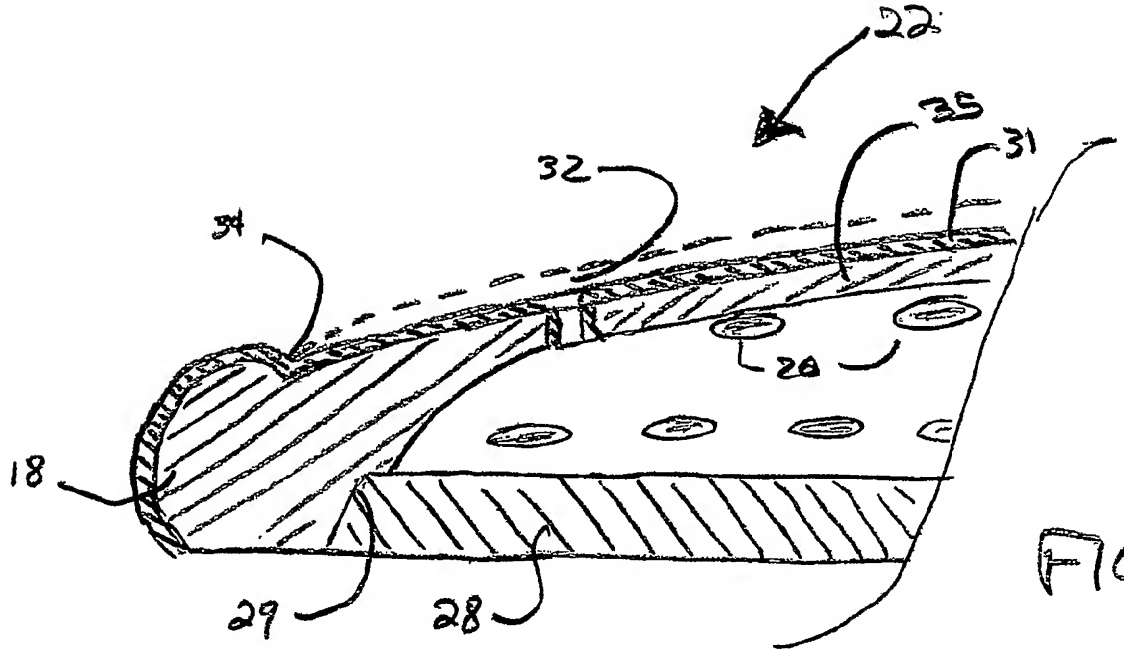


FIG. 4B

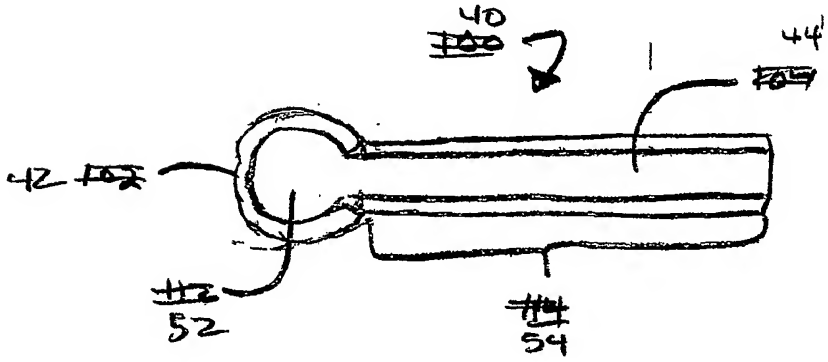


FIG. 5A

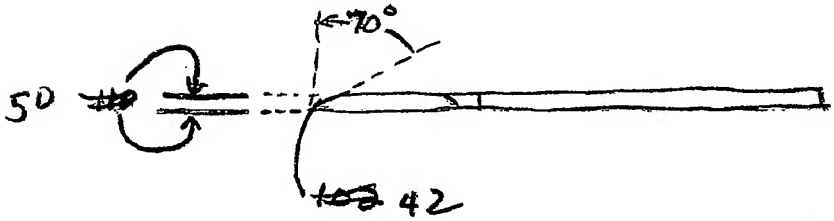


FIG. 5B

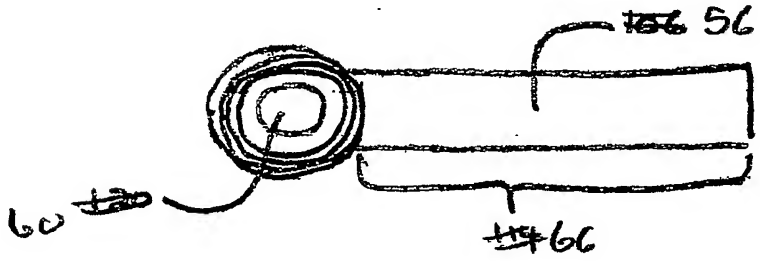


FIG. 5C

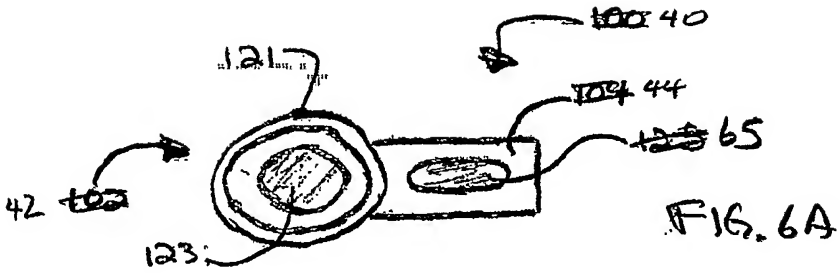


FIG. 6A

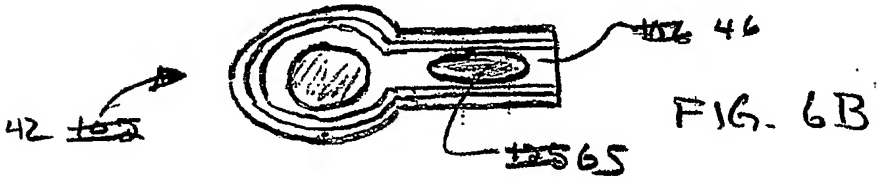


FIG. 6B

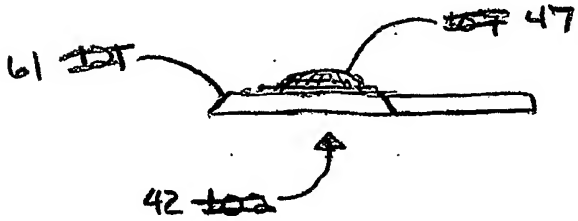


FIG. 6C

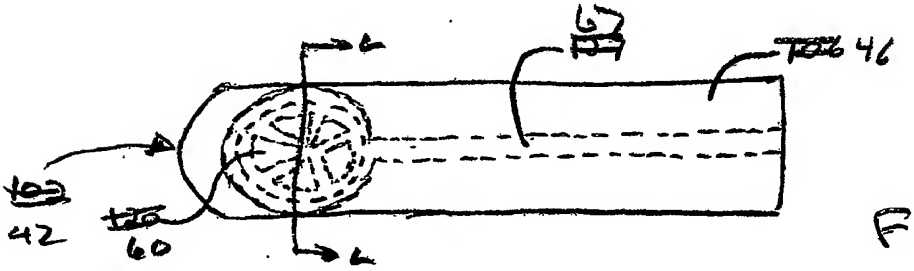


FIG. 7A

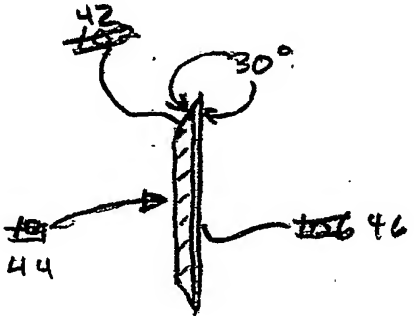


FIG. 7B

FIG 8A

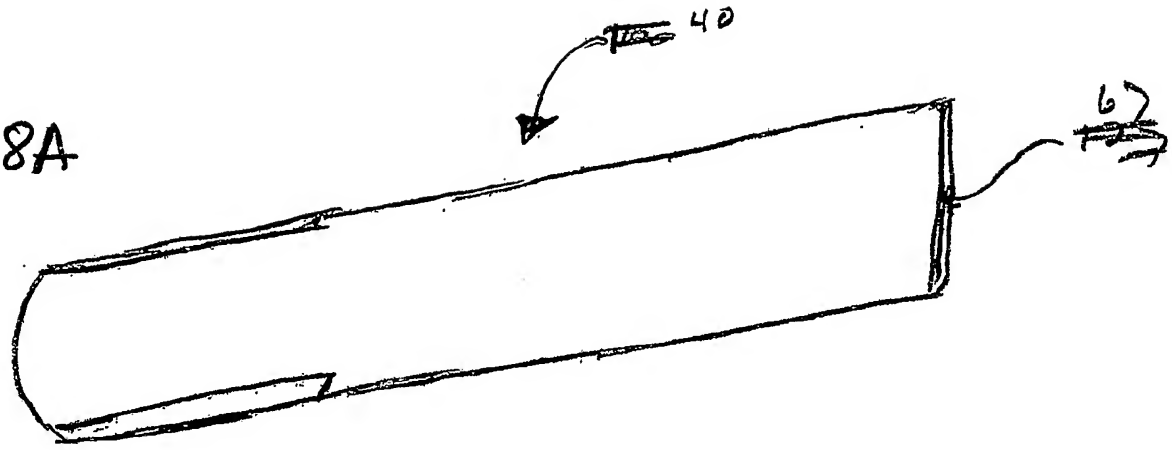


FIG 8B

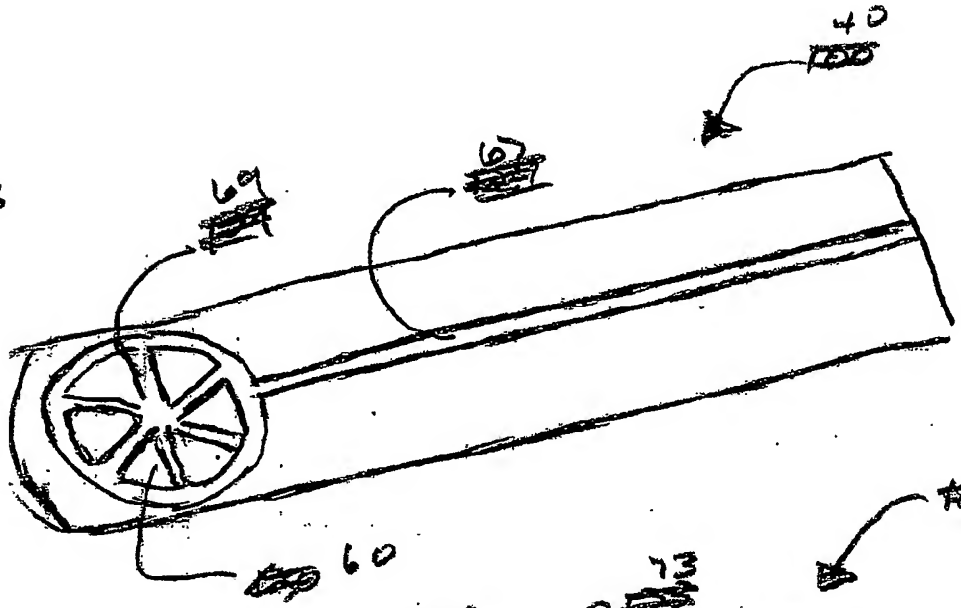
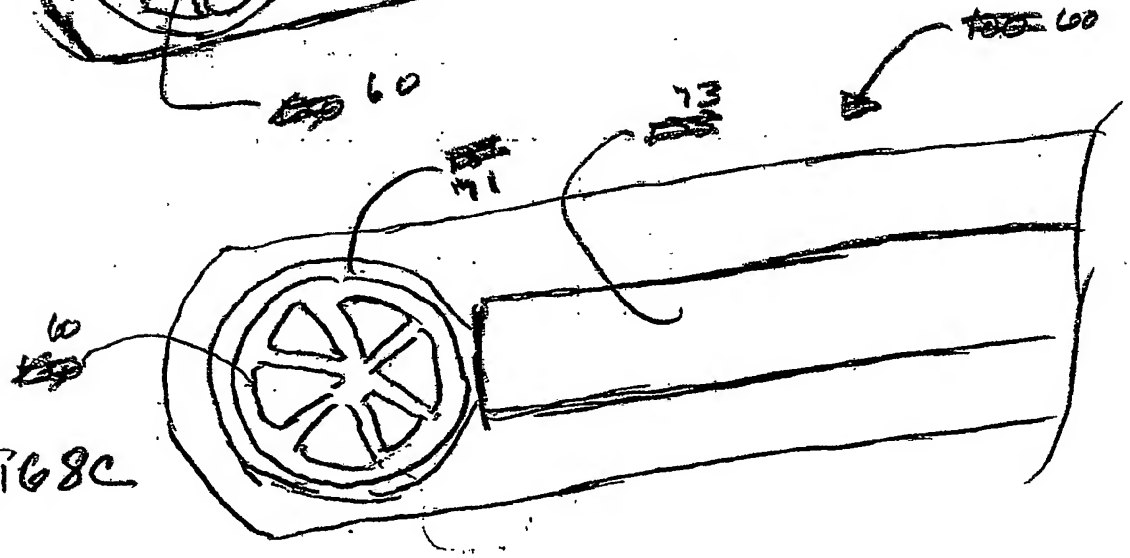


FIG 8C



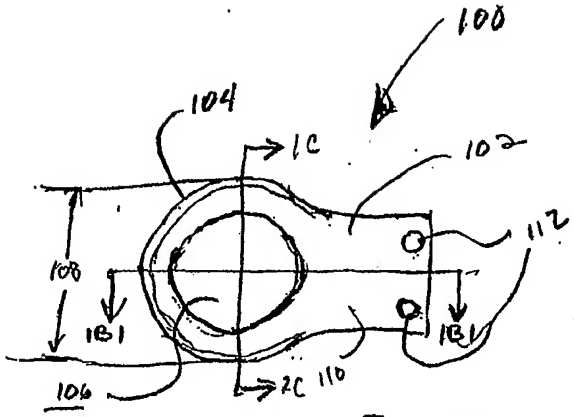


Fig. 9A

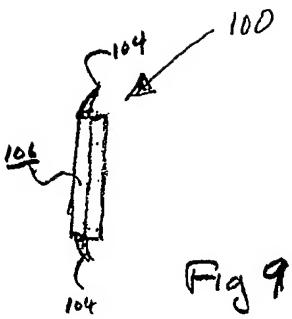


Fig 9C

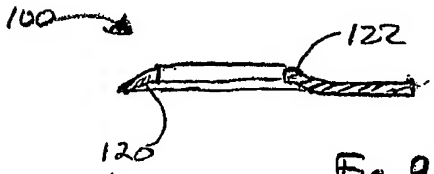


Fig. 9B2

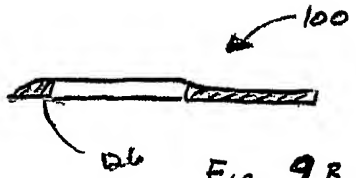


Fig. 9B2

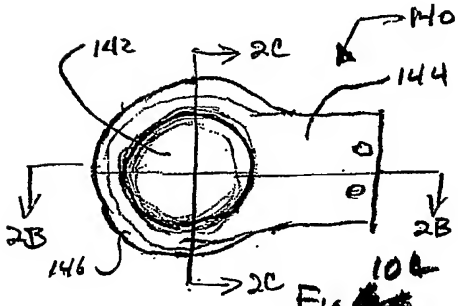


Fig 10A

Fig. 10C

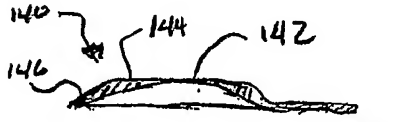


Fig 10B

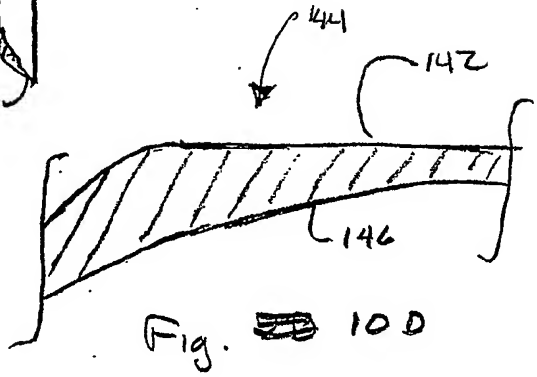


Fig. 10D

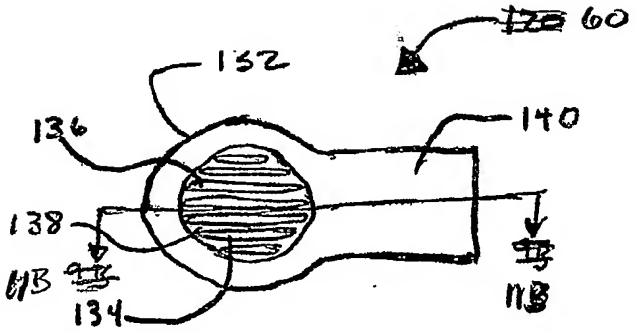


FIG. 11A

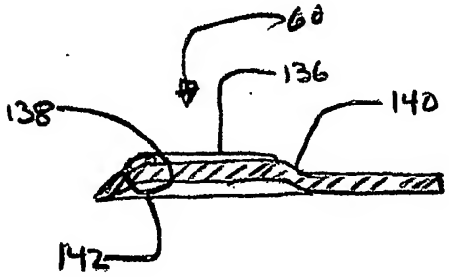


FIG. 11B

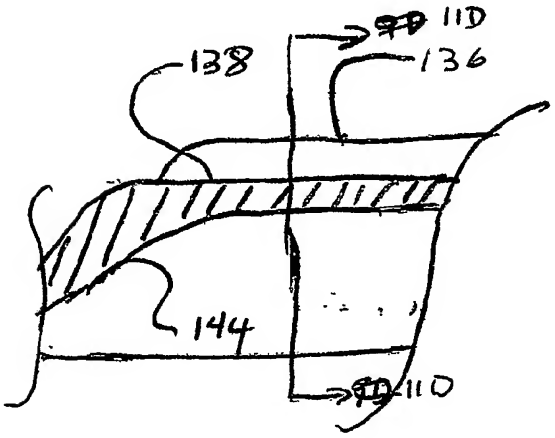


FIG. 11C

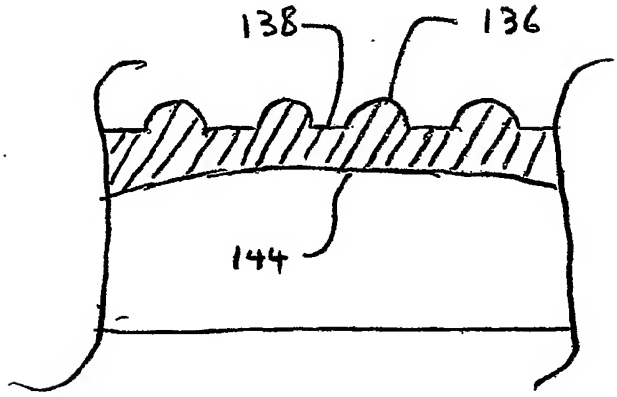


FIG. 11D

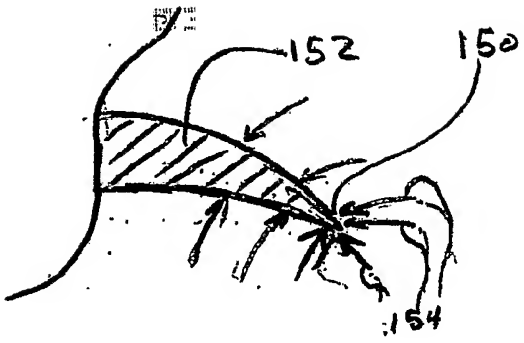


FIG 12A

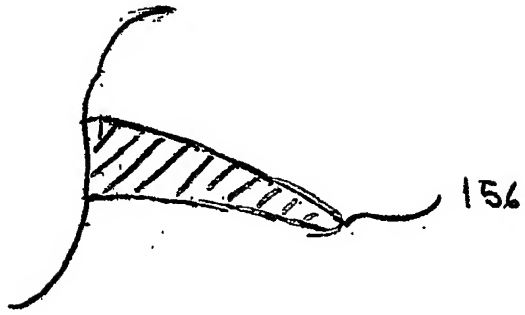


FIG 12B

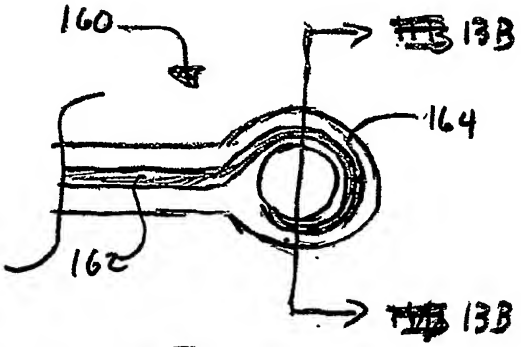


FIG. 13A

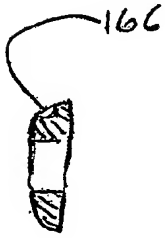


FIG. 13B

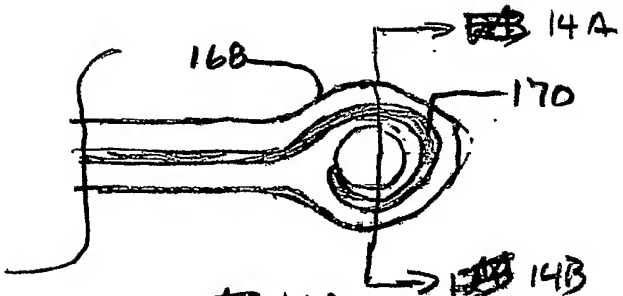


FIG. 14A

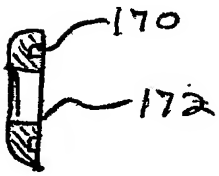


FIG. 14B

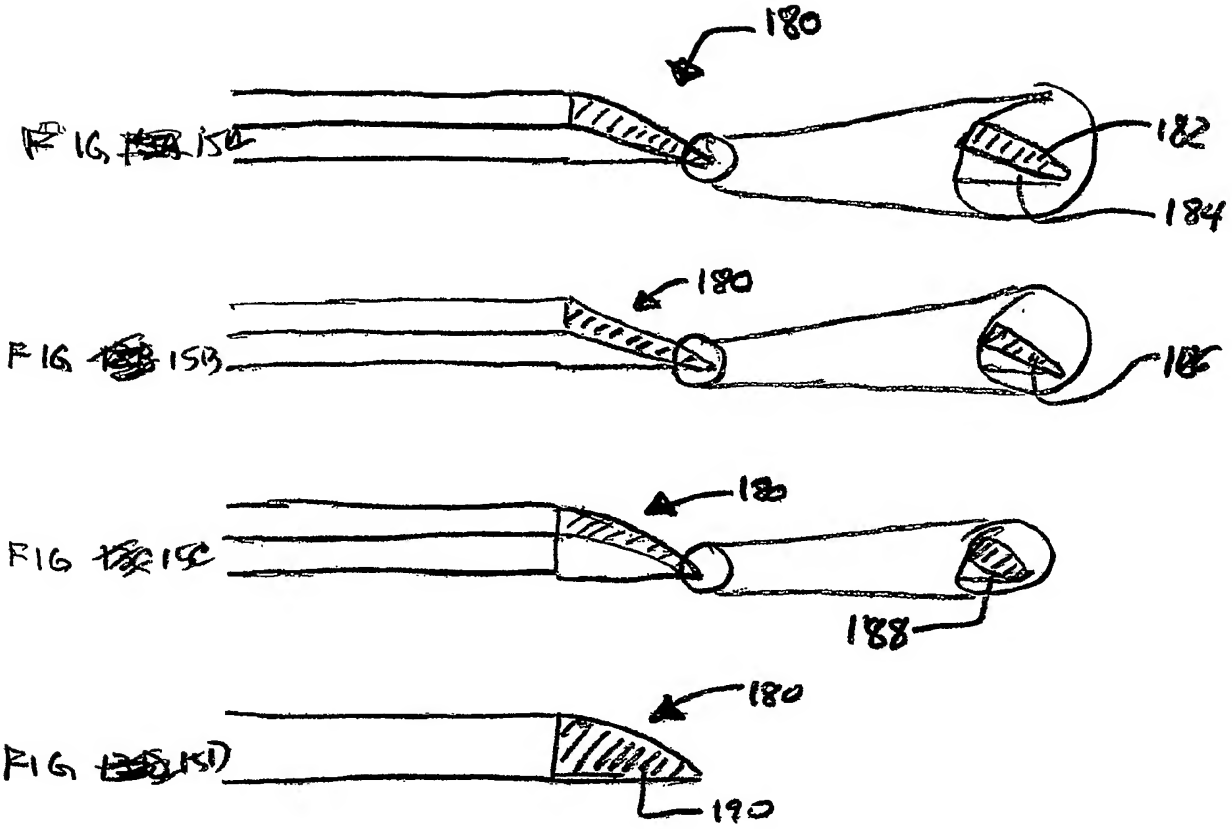


FIG. 15A

FIG. 15B

FIG. 15C

FIG. 15D

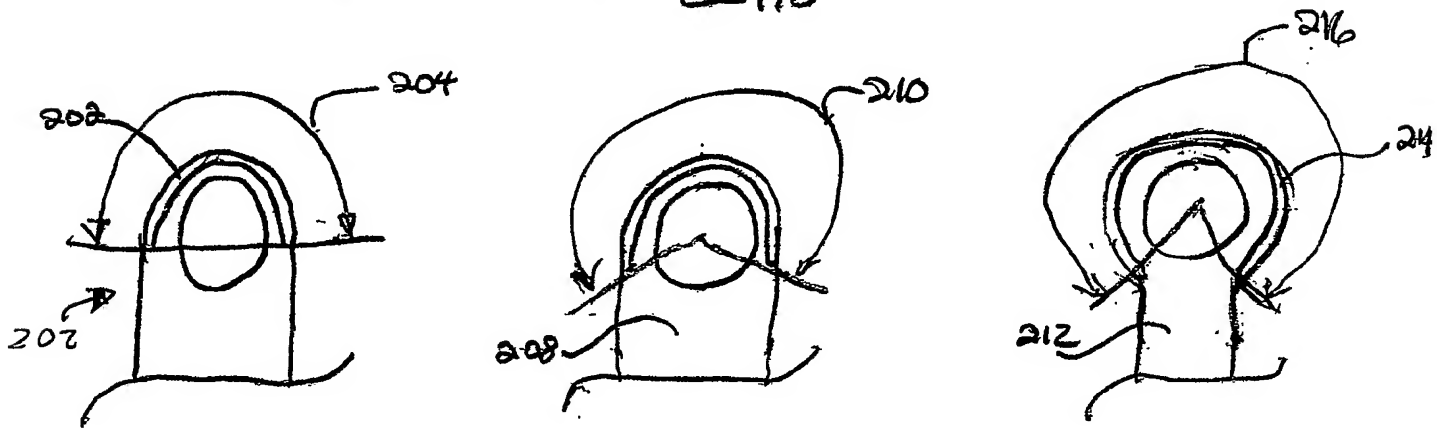


FIG. 16A

FIG. 16B

FIG. 16C

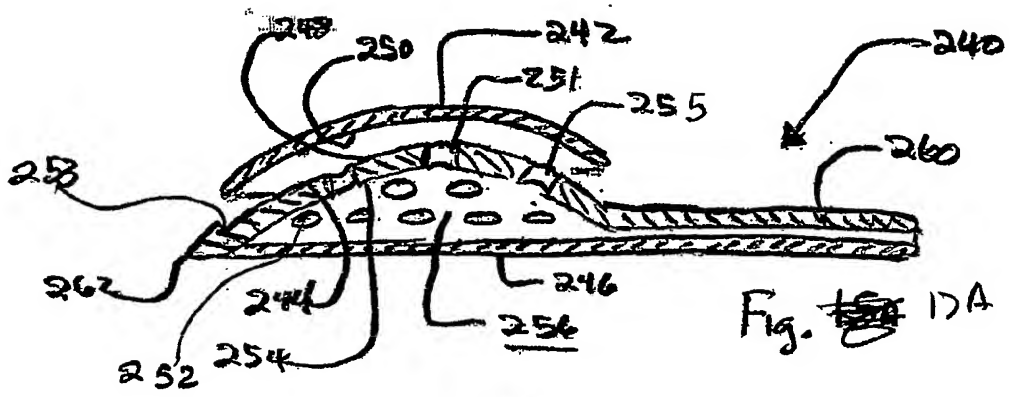


Fig. 1A

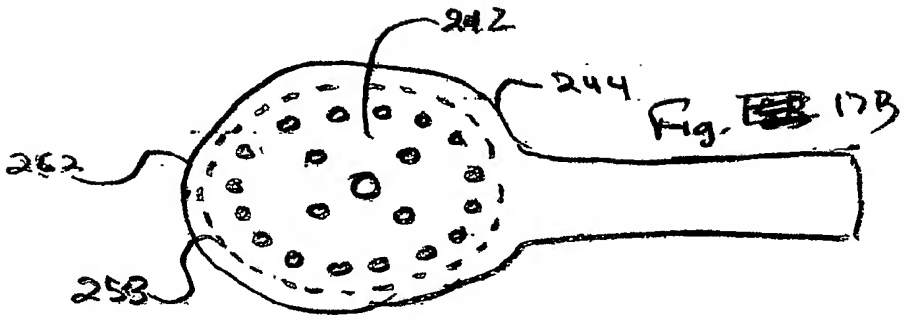


Fig. 1B

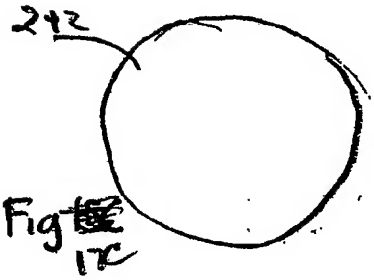


Fig. 1C

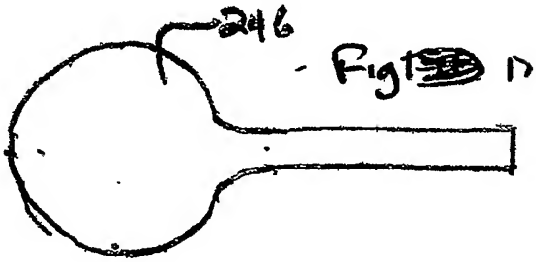


Fig. 1D

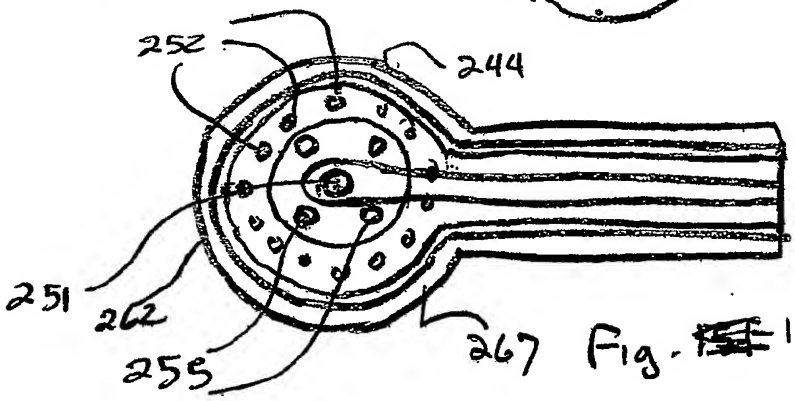


Fig. 1E

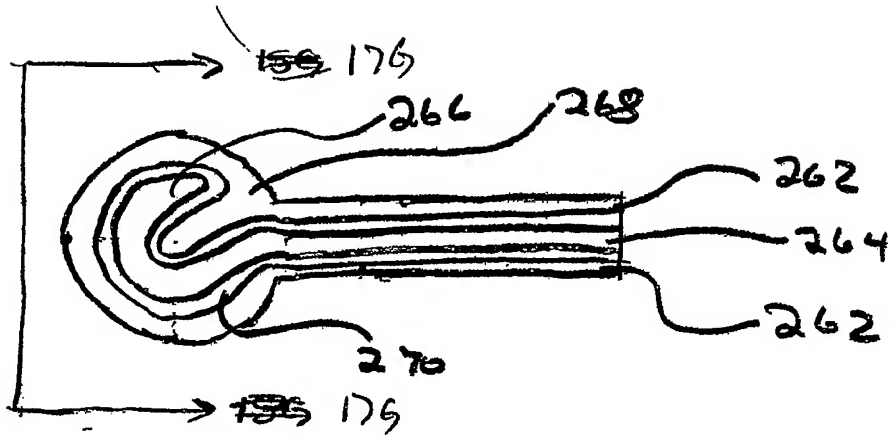


FIG. 17F

FIG. 17G

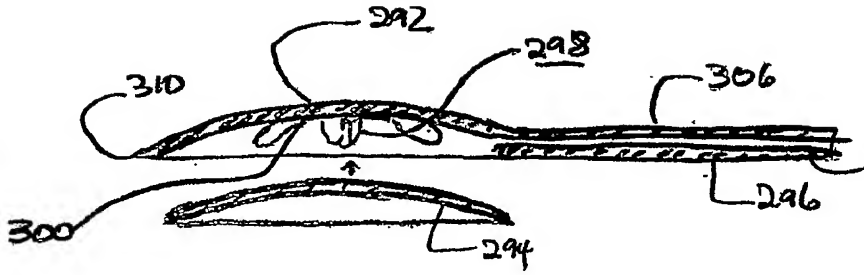


FIG 18A

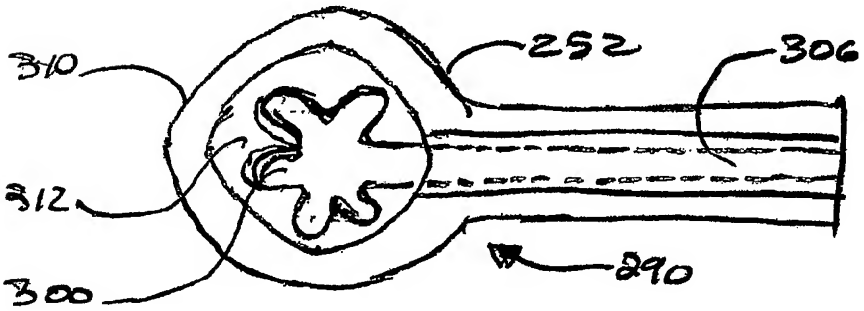


FIG 18B

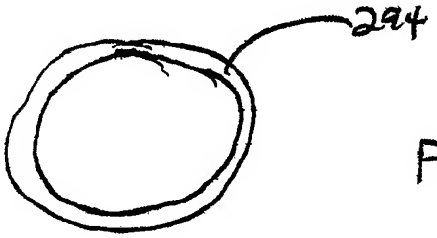


FIG 18C

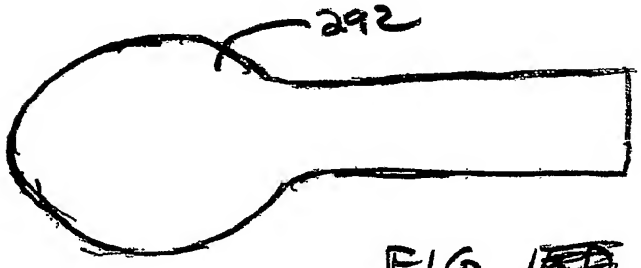


FIG 18D

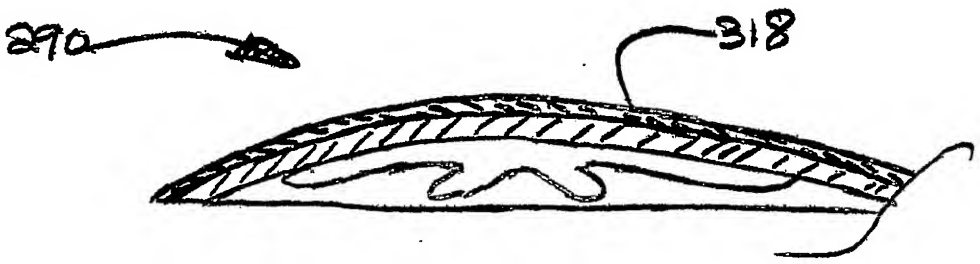


FIG. ~~18E~~ 18F

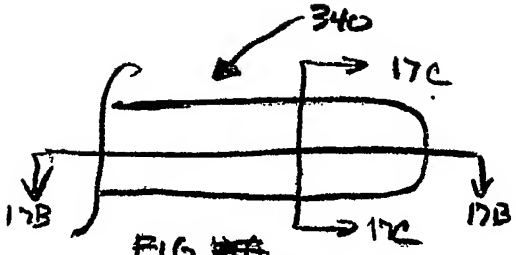


FIG 19A

FIG 19C

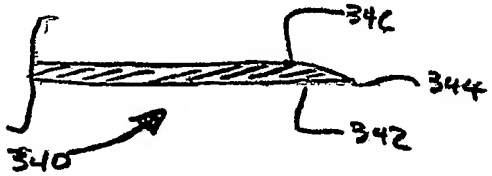


FIG 19B

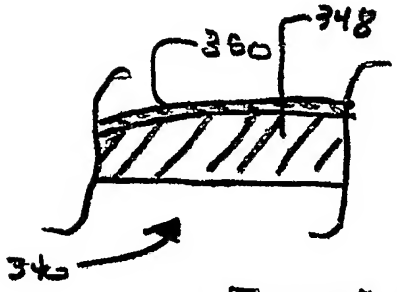


FIG 19D

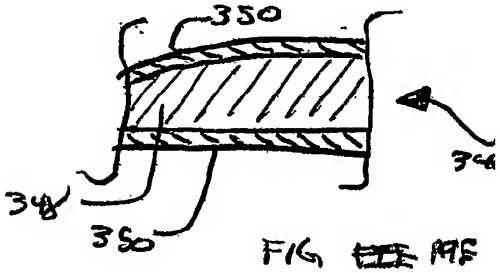


FIG 19E

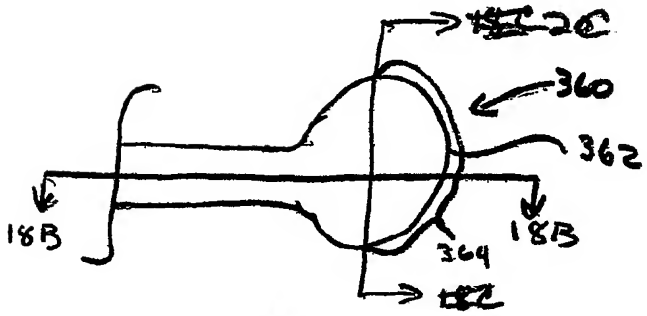


FIG 20A

FIG 20C

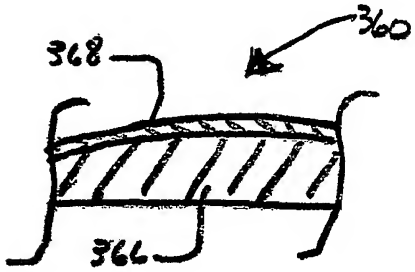


FIG 20D

FIG 20B

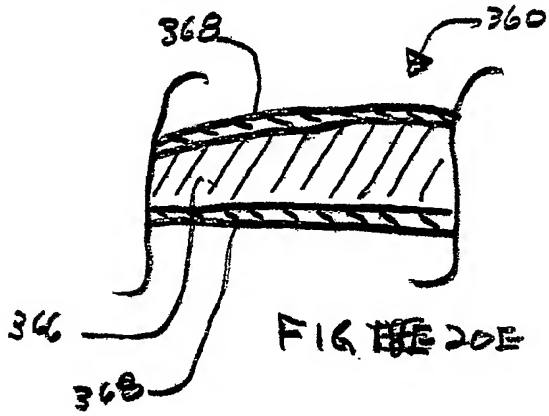


FIG 20E

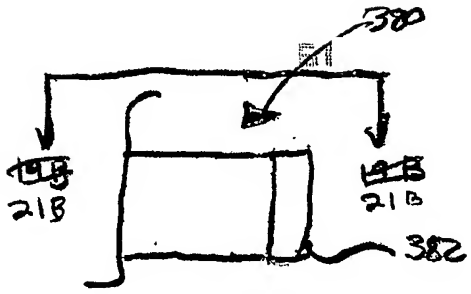


FIG 21A

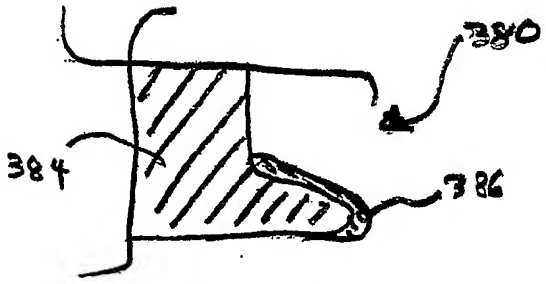


FIG 21C

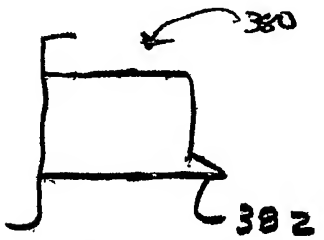


FIG 21B

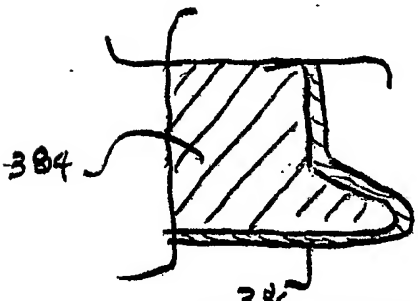


FIG 21D

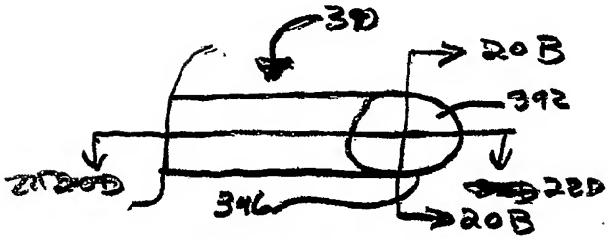


FIG 22A

FIG 22B

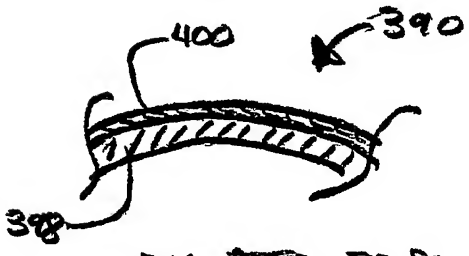


FIG. 22F

FIG 22C

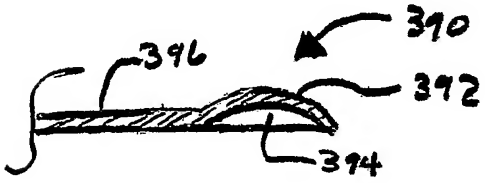


FIG 22D

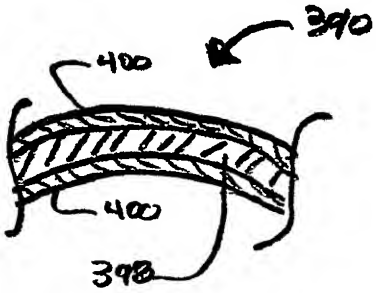


FIG. 22F

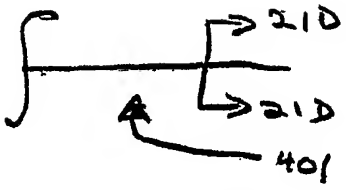


FIG 23A

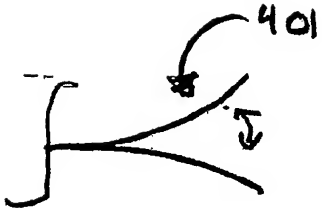


FIG 23B

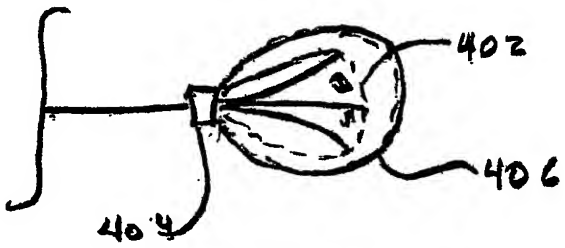


FIG 23C

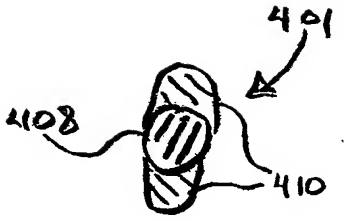


FIG 23D

FIG 23E

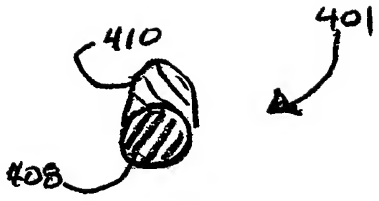


FIG 23F

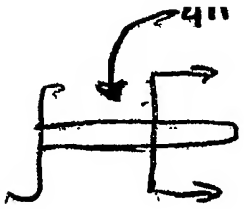


FIG. ~~22A~~ 24A

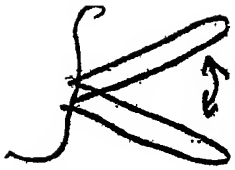


FIG. ~~22B~~ 24B

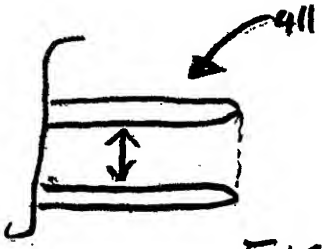


FIG. ~~22C~~ 24C

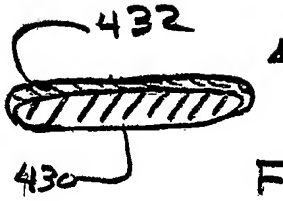


FIG. ~~22F~~ 24F

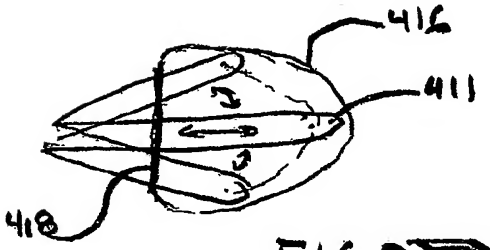


FIG ~~22D~~ 24D

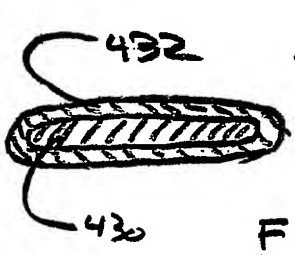


FIG. ~~22G~~ 24G

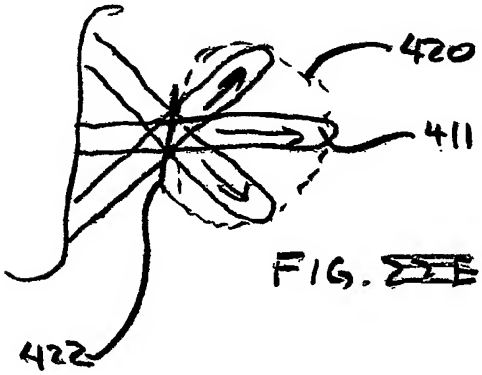


FIG. ~~22E~~ 24E

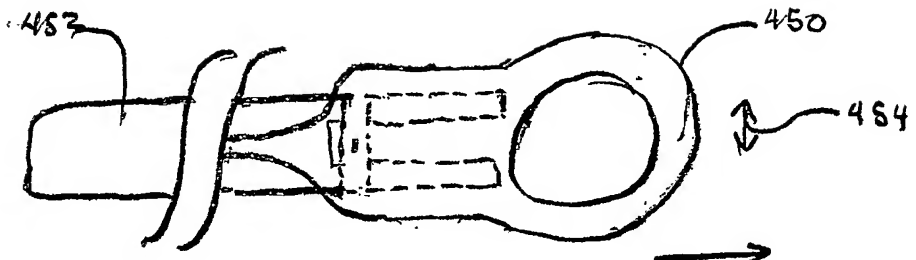


FIG 25A

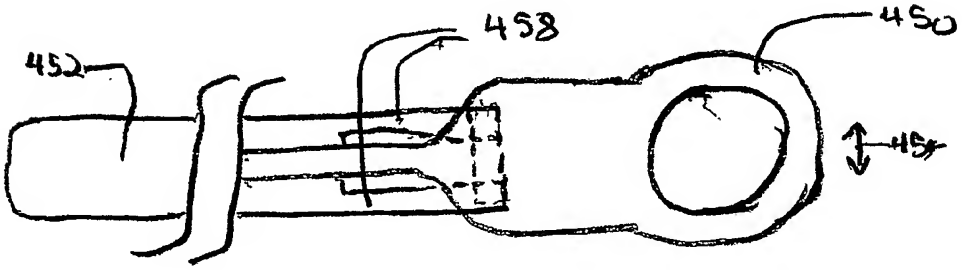


FIG. 25B

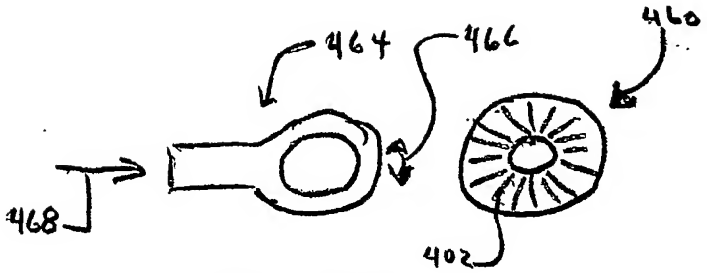


FIG. 26A

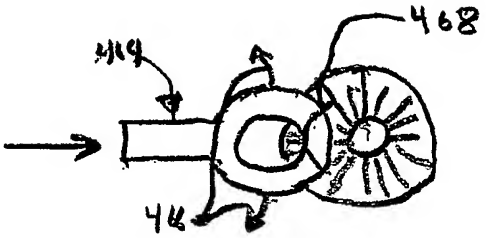


FIG. 26 B

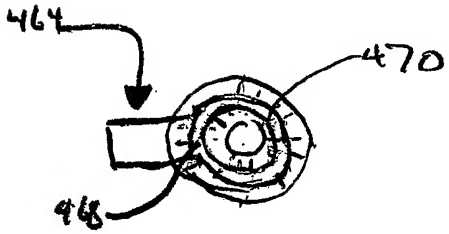


FIG. 26C

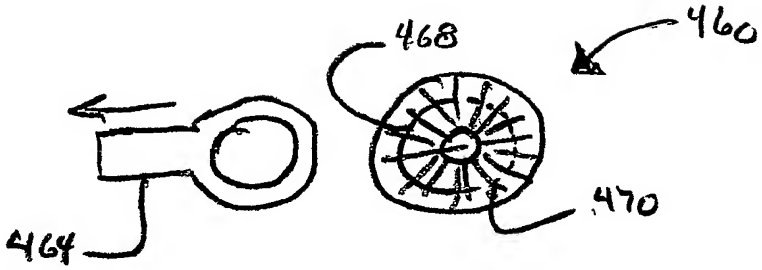


FIG. 26 D